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**SOS lobby ups
pressure over
SGM agenda**

**PSNI members
face 13pc rise
in annual fees**

**Numark rebate
rises 58pc to
£6,000 average**

**Managing risk
– spotting and
limiting hazards**



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© CMP Information Ltd
Chemist & Druggist incorporating Retail
Chemist, Pharmacy Update and Beauty
Counter

Published Saturdays by
CMP Information Ltd,
Sovereign Way,
Tonbridge, Kent TN9 1RW

C&D on the internet at
<http://www.dotpharmacy.com/>

Subscriptions (Home) £155 per annum;
(Overseas & Eire) £369 per annum including
postage, £2.60 per copy (postage extra)
Additional Price List: £100 per annum

Circulation and subscription:
CMP Information Ltd, Tower House,
Sovereign Park, Lathkill St, Market
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Telephone: 01858 438809
Fax: 01858 434958

Refunds on cancelled subscriptions will only be
provided at the publisher's discretion, unless
specifically guaranteed within the terms of
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SOS campaign may resort to the law

Pharmacists opposed to the Royal Pharmaceutical Society's modernisation plans say they are prepared to turn to the law, should more constitutional methods fail to change the Society's current stance.

The move to consider legal action aims to establish whether alternative legal positions regarding the Society's modernisation plans exist, according to Birmingham pharmacist and Young Pharmacists' Group advisory panel member Mark Koziol. "It may be that the Society's legal position is not the only one in town," he said.

Since the launch of the 'Save Our Society' campaign last month, when seven Council candidates openly declared their opposition to the RPSGB's approach to modernisation (*C&D*, April 26, p4), around £10,000 has been spent on more 'constitutional' methods of effecting change. These include two websites:

saveoursociety.org.uk and <http://saveoursociety.blogspot.com>, a mail out to 10,000 pharmacists

registered as living within travelling distance of London and a newsletter.

According to Mr Koziol, the financial support is said to be coming from a wide range of sources, from the well-placed politically and commercially, as well as ordinary pharmacists, many of whom wish to remain anonymous.

The saveoursociety.org.uk site, which is registered in the name of YPG executive member Kevin Frost, states that: "The professional and regulatory body of pharmacists is in danger of losing its chartered purpose to safeguard and promote the interests of the membership in their exercise of their profession." Written as a personal initiative, but with input from the YPG, the website encourages pharmacists to attend the Special General Meeting on the RPSGB's modernisation plans on June 1.

The mailout, sent out in the first week of May, highlights the seven 'SOS' candidates and their concerns about the RPSGB's modernisation proposals. It says: "If you share these concerns it is

No lack of consultation

The Society's secretary and registrar, Ann Lewis, has said that the modernisation process has been subject to a widespread consultation, and that pharmacists have had every opportunity to comment on the proposals.

"The Society has consulted widely on the changes that will support the profession in the future. There has already been much debate and this continues

with the discussions on the proposals for a new Royal Charter. The Society is giving pharmacists every opportunity to learn about the changes and to provide feedback to the process. We are doing this in a variety of ways including running a series of national 'Fit for the Future' roadshows, funding special Branch meetings and providing articles to the pharmacy media," she said.

vital that you vote for every one of them." It also encourages members to vote at the SGM.

YPG chairman Noel Wicks described the SOS campaign as "a theme people seem to want to get to grips with" although Numark chief executive David Wood said that initial canvassing of its members' opinions has yielded "diversity in views on the Society, its role and the proposed new Charter". He said that a number of central office pharmacists would be attending the SGM.

SOS Council candidate

Nicholas Wood reported sympathy for SOS ideals among local pharmacists in Essex. He said pharmacists should not consider SOS as a destructive campaign.

"SOS is not about wrecking everything that Council is doing but to see whether there are viable alternatives. The people involved in the campaign have been in responsible positions and know quite a lot about the inside workings of the Society and are not happy about what's being done in our name," he added.

MULTIPLES

Moss sponsors student awards

Three financial awards supporting students through their pharmacy studies are now available from Moss Pharmacy.

Part of the new Moss Pharmacy Charitable Trust, set up in memory of Harold and Marjorie Moss, the awards offer financial help for students unable to start or complete a pharmacy undergraduate degree due to financial constraints, PhD students undertaking research to benefit community pharmacy, and for Moss Pharmacy dispensers with a place to study for a pharmacy degree but who are in financial need.

The awards are discretionary and there is no finite limit to the number of awards available and, as it is a charitable trust, the recipients of the awards will be

under no obligation to work for the company when training is complete.

The awards will be made in time for the academic year starting autumn 2003 and comprise a limited number of undergraduate awards for up to £5,000 per year of study; one £5,000 PhD award and several Moss Pharmacy dispenser awards for up to £7,500 per year throughout the course. Schools and colleges will be contacted on an individual basis for potential award candidates.

Barry Andrews, Moss Pharmacy non-executive chairman, said: "It was Harold and Marjorie's strong desire to assist impoverished students to reach their goal of qualification in pharmacy."



Marjorie Moss, who died last year, with (left) Barry Andrews and Alliance UniChem board chairman Jeff Harris



The OFT report must be getting too much for Howard Stoate, MP – he's taken to hurling himself off London landmarks. The chairman of the All-Party Pharmacy Group was last seen abseiling down the Tate Modern Gallery along with parliamentary colleagues Dr Liam Fox and Andrew George. However, Dr Stoate may also have been helping to launch the National Asthma Campaign's 10-point asthma charter – a plan outlining the rights that people with asthma should expect to receive from the NHS

Register restructure proposed

The Royal Pharmaceutical Society's Council has recommended that the pharmaceutical register be restructured to have "active" and "inactive" categories of pharmacists to reflect future CPD requirements.

At a meeting on April 30, Council considered the issue of CPD for pharmacists. It recommended that, as well as having an "inactive" category of pharmacists on the register who were not subject to a CPD requirement, that:

- CPD be mandatory for those undertaking a job that legally requires them to be a pharmacist or that is usually undertaken by a pharmacist, and for those undertaking a pharmacy or healthcare job for which they do not have to be a pharmacist
- CPD not be mandatory for those who have retired, are on an extended career break, or who are not active in pharmacy
- pharmacists who are inactive/non-practising should be required periodically to sign an undertaking that they are not, and will not, engage in pharmacy practice or proffer pharmaceutical or healthcare advice; and also that "inactive" pharmacists must qualify that they are non-practising when they describe themselves as a pharmacist; and
- CPD records must, as a minimum, relate to pharmacy in general and should also relate to the pharmacist's sector of employment; also every pharmacist's CPD record must include reflection on – or the application of learning and development of – pharmacy science or practices.

N Ireland pharmacists face 13pc retention fee rise

The Pharmaceutical Society of Northern Ireland is consulting its members on a proposal to increase retention fees by 13 per cent.

Pharmacists have until May 23 to comment on the proposal, which was passed by the Society's Council in April. If the rise is accepted, the fee for full membership will be £170; overseas membership will be £78; members 65 years and over £62;

70 and over £28; while the restoration fee will rise to £255.

PSNI has also proposed a part-time fee of £100 for pharmacists under 65 and working 13 weeks or fewer per year.

According to PSNI chief executive Sheila Maltby, the fee increase is due to priorities identified in the Society's three-year business plan.

These include:

- the appointment of a CPD facilitator, towards which PSNI has committed £6,000 in the first year
- a communication strategy to tell members about CPD, which will cost £2,000
- employing support staff to enable the Society to undertake development work for its modernisation programme at a cost of £10,000.

Risk sharing scheme for MS drugs will miss target

A scheme in which the Government and the pharmaceutical industry share the cost of drugs for multiple sclerosis patients will miss its target of recruiting 9,000 patients by this November, according to one of the scheme stakeholders.

Under the risk-sharing scheme, which was launched last year to allow MS patients access to

disease modifying treatments (DMTs), the prices paid for the drugs by the NHS varies depending on whether expected patient benefits are realised.

It was estimated that 9,000 patients (15 per cent of MS patients) would be eligible under the Association of British Neurologists' guidelines to receive treatment under the scheme,

following a statutory direction issued by ministers, which placed NHS bodies under a funding obligation equivalent to that for positive NICE guidance.

However, the latest figures show that only 1,118 people have been recruited onto the scheme since May 2002, and according to Schering Health Care's marketing director Mark Gibson the

November target is "definitely not going to be hit".

He cited lack of PCT funding, lack of local resources, logistics and infrastructure, communication problems between the DoH and clinicians, and limited best practice sharing, as some of the reasons for the delay in reaching the target. (See p14 for Mark Gibson's comment).

Scottish concerns about Charter

Pharmacists in Scotland are concerned that some of the proposals in the RPSGB's draft Charter could have damaging consequences for the profession if implemented north of the border.

The Scottish Pharmaceutical General Council wrote to Christine Gray, modernisation project manager, at the end of April raising these concerns.

In his letter, Frank Owens, chairman of the SPGC, warns that the continued success of the profession in Scotland depends on recognising the changing face of Scottish society.

He says that the Scottish executive of the RPSGB will require a greater degree of autonomy than it currently has. "We do not consider that the Society can be expected to fully appreciate the subtle nuances of NHSScotland from afar.

"If pharmacy is to maximise the gains afforded by opportunities presented in a future Scottish healthcare framework, effective responsibility must be delegated to the Scottish Executive. Failure to do so will not serve the needs of the Society's Scottish electorate, and will result in missed opportunities."

It is also essential that the RPSGB continues to recognise "a separate and distinct need" for a suitable Scottish structure within the new Charter, he added. However, Article 6(4) of the proposed draft of the new Charter, replaces Article 16 of the 1953 Charter with: "The Council shall have power by regulation to establish, dissolve and regulate any form of geographical or other subdivision of the Society."

● The closing date for comments on the Charter is September 5.

Motion proposed for Scottish AGM

A motion about the RPSGB's draft Charter has been proposed for the annual general meeting of the Scottish Department on June 18 in Edinburgh.

Maurice Hickey's motion says: "It is the opinion of the members of the Scottish Department that the new Charter of the RPSGB must take account of devolution and in particular NHSScotland.

"The Scottish members require that their elected Scottish Executive should be allowed the powers to make policy for Scottish pharmaceutical and health matters.

"The Scottish members require that these changes should be explicitly written into any new or amended Charter."

Mr Hickey said: "The Scottish

Department hasn't been written out of the Charter but, at the same time, it hasn't been written in."

"Although other people say it has been left that way because devolution may occur in England, devolution is a reality in Scotland and we feel very strongly that the Charter should take account of that."

Mr Hickey said there is also the problem that only the Council can make policy. "That's caused problems since the Scottish Parliament started where the Scottish Department and members are wanting to respond to consultations and have been unable to because Lambeth doesn't have a line, or hadn't developed a line."

CPP chairman Angela Alexander with Greg Condry, the London regional director of the NHS University, who gave the College Day annual address. The NHSU will attract a large number of students, he anticipated, and will bring common standards and relevance to NHS training. The NHSU will operate in Wales and Northern Ireland, and expects to issue its first prospectus in September. The first courses will be rolled out in November, with a pilot year before a "mass offering"



PRACTICE

Mentoring role for CPP

The College of Pharmacy Practice has set itself the target of establishing a mentoring scheme in 2003.

College chief executive Ian Simpson, speaking at the College Day last week, said a place for a CPP mentoring scheme had been identified as one way of supporting the CPD portfolio being rolled out to 10,000 pharmacists by the RPSGB this year.

The CPP is looking to promote mentoring as part of its CPD for practitioner members. It is also proposing to provide training to support a UK-wide mentoring network. "We may even offer payment for mentoring, if users are prepared to pay for such a service," said Mr Simpson.

● Most mentoring schemes collapse through lack of support within two years, according to Steve Howard, director of training and development, Lloydspharmacy.

However, the scheme the company set up at its head office in 2001 is still in place, albeit after major review. The initial scheme was found to be over-managed and involved too much paperwork.

Questiontime

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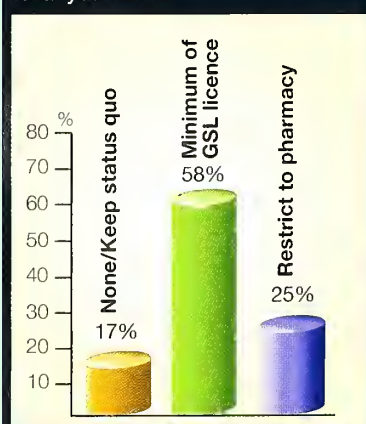
Last week we asked you: "What controls on VMS sales do you think are appropriate following the new guidance? You replied (see right):

This week's question: Northern Ireland pharmacists face a 13 per cent increase in retention fees. Do you think the increase is:

- About right
- Too high
- Too low

You can record your vote on our website: mm.dotpharmacy.com. You have until noon on May 20 to cast your vote. We will publish the results in C&D, May 24.

What you told us



All-round airborne allergy relief in your pharmacy

Airborne allergy (allergic rhinitis) sufferers can benefit from so much more than conventional therapy. After all, only 26% of people surveyed reported that their symptoms were well or completely controlled, despite self treatment.¹ Now you have an opportunity to up the anti and make a difference.

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So much more than a hayfever treatment

Flixonase Allergy Nasal Spray provides relief from seasonal and non-seasonal airborne allergies, due to inhaled particles of pollen (hayfever), animal dander, house dust mites, mould spores and allergies exacerbated by pollution.¹¹ It can also be used to prevent further attacks during allergen exposure.¹¹

So much more than relief of nasal symptoms

Airborne allergy can lead to a wide range of unpleasant symptoms of the eyes, nose and head, from early phase



(within minutes) to late phase (within hours).^{12,13} It's not just irritating; nasal congestion and sinus discomfort can cause disturbed sleep and affect people's mood and ability to function properly during the day.¹²⁻¹⁴

Flixonase Allergy Nasal Spray provides up to 24 hours' relief from a wide range of symptoms:

- Early ● itchy eyes ● runny nose ● sneezing³⁻⁸
- Late ● nasal congestion ● sinus discomfort ● groggy headed feeling^{3-7,9,10}

It is important to note that Flixonase Allergy Nasal Spray works as well as antihistamines at relieving eye symptoms.^{3,8} But nothing is more effective than Flixonase Allergy Nasal Spray at relieving nasal symptoms and nasal blockage,^{5,7} and so helping to relieve associated blocked up or groggy feelings.¹⁰ And all in a simple, once-daily dose. What more could your airborne allergy sufferers ask for?

Now you can be anti allergy in your approach to symptom relief



fluticasone propionate

Flixonase Allergy Nasal Spray Product Information. **Presentation:** Aqueous nasal spray suspension containing 50 micrograms of fluticasone propionate per spray. **Uses:** Prevention and treatment of allergic rhinitis. **Dosage and administration:** Intranasal use only. **Adults and the healthy elderly:** Two sprays into each nostril once a day, preferably in the morning. Use twice daily if required. Do not use more than 4 sprays a day in each nostril. Prophylaxis of allergic rhinitis requires treatment before contact with allergen. **Children under 18 years:** Not to be used. **Contraindications:** Known hypersensitivity to ingredients. **Precautions:** If symptoms have not improved after 7 days or, if symptoms have

improved but are not adequately controlled, consult a doctor. Not be used for more than 3 months continuously without consulting a doctor. **Consult a doctor before use in:** concomitant use of other corticosteroid products, nasal/sinus infection, recent nasal injury/surgery, nasal ulceration. Risk of adrenal suppression with higher than recommended doses. Significant interactions between fluticasone propionate and potent inhibitors of the cytochrome P450 3A4 system, e.g. ketoconazole and protease inhibitors, such as ritonavir, may occur. This may result in increased systemic exposure to fluticasone propionate. **Side effects:** Dryness and irritation of the nose and throat, unpleasant taste and smell, headache and epistaxis. Hypersensitivity reactions including

skin rash and oedema of the face or tongue. Rarely anaphylaxis/ anaphylactic reactions and bronchospasm. Extremely rarely nasal ulceration and nasal septal perforation usually following previous nasal surgery. **Pregnancy and lactation:** Do not use except with medical advice. **Legal category:** P. **Product licence number:** PL 10949/0360. **Product licence holder:** Allen & Hanburys, Stockley Park, Middlesex, UB11 1BT. Further information available on request from Medical and Consumer Affairs, GlaxoSmithKline Consumer Healthcare, Brentford, Middlesex, TW8 9GS. **Package quantity and RSP:** 60 spray pack £6.79. **Date of preparation:** December 2002. Flixonase is a registered trademark of the GlaxoSmithKline group of companies.

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Report Nucare Convention

Watch out for back door regulation

Leading pharmacy politicians have warned yet again that the 'balanced package of measures' being sought by the Department of Trade – after its rejection of the OFT's recommendation to deregulate the pharmacy sector – could achieve the same result by the back door.

Both NPA chief executive John D'Arcy and PSNC chairman Barry Andrews, speaking at the Nucare Convention near Coventry last weekend, warned that the political momentum against such an outcome must be maintained until the Government publishes its proposals at the end of June.

"It has been clear that changes will be needed – OFT or not – as a consequence of *Pharmacy in the Future*," said Mr Andrews. PSNC has proposed four areas for change which "give balance to the interests of patients, pharmacies and the NHS", and which have put forward in discussions with the DoH and the NHS Confederation, which represents PCTs:

- rather than remove PCT powers to control the location of pharmacy services, they should be strengthened
- under the present arrangements, 'no cost'

appeals are often lodged against contract applications as a delaying tactic. PSNC proposes there should be a charge for appeals

● although it wants PCTs to contract with pharmacies for services using national templates, PSNC says contractors will still compete on the quality of the service and any additional elements agreed locally

● PSNC proposes that LPCs should have a duty to secure delivery of unmet needs that a PCT wishes to provide.

Mr Andrews also said there was still a question mark over whether the DoH proposals would apply across the UK, despite a recent statement in the Commons by DTI minister Melanie Johnson in which she said regulations on control of entry are devolved to Scottish ministers (*C&D* May 10, p5).



Supply role leaves pharmacies vulnerable

Community pharmacists need a new NHS contract because sticking with a simple supply role makes businesses vulnerable if the NHS switches to direct supply, NPA chief executive John D'Arcy has warned.

The Welsh Auditor General says centralised buying of 300 primary care medicines could save NHS Wales £50 million a year, and the Welsh National Assembly has been considering whether to pilot centralised buying (*C&D* March 29, p10).

Direct supply of dressings is being looked at in the Isles of Scilly and Hertfordshire.

"A supply role makes pharmacies vulnerable," said Mr D'Arcy. "We need to build services around it. The professional future is about a clinical role."

For years pharmacists have been looking for recognition. That is now happening with the various national pharmacy strategies, "but we now have to perform or we are out of the game", he said.

"We have been looking for recognition for years. That is now happening with the various national pharmacy strategies, but we now have to perform or we are out of the game", he said.

In the political arena pharmacy has gained profile hugely on the back of the investigations by the OFT into RPM and control of entry. "It is easy to be daunted by the agenda, but we have a great opportunity."

Pharmacists need to demonstrate they add value in primary care, he said, and promote the clinical quality of their services –

not the size of the prescription bill.

They need to upgrade the standards of their premises, and provide consultation areas. This will be a requirement for any provision of tier 2 services under the new contract, said Mr D'Arcy, and only 25 per cent of pharmacies currently have such facilities.

Good record keeping must become the norm to enable any sort of medicines management. Pharmacists and their staff must demonstrate competence through CPD, and get involved in clinical governance issues.

There are also issues primary care organisations need to address, said Mr D'Arcy. They must integrate pharmacy into their local plans, and involve community pharmacists in strategic planning.

"PCT-driven services have tended to be ad hoc, and pharmacy has tended to be an afterthought. This has got to stop. It is still a serious omission that pharmacists have not got a place on the boards of PCTs."



NPA

Out-of-hours only where clinical need

Pharmacy bodies are insisting GPs should supply medicines out-of-hours only if there is an immediate clinical need and the patient cannot wait until the next day.

Similar standards should apply to full courses of medicines supplied out-of-hours as those supplied in normal hours – that is, the medicines should have been stored and labelled correctly and a patient information leaflet supplied.

The NPA and PSNC have been working closely with the Department, and insisting that out-of-hours schemes should have guaranteed probity. There should be arrangements for all prescription charges to be collected, and monitoring for charge evasion.

The DoH will issue guidance on out-of-hours supply soon, the NPA Management Board heard at its last meeting.

NPA

Government endorses pharmacy EHC supply

Community pharmacy supply of emergency hormonal contraception is safe, effective and working well, the Government has declared.

Speaking in the House of Lords recently, Government health spokesman Baroness Andrews said there is no evidence, information or feedback that EHC is being supplied by pharmacists without proper health checks and said that pharmacists are committed to offering an excellent advice service. "We are content the system is safe and is working well. Pharmacists are in a good position to give sound advice because they are part of the community and people are confident in dealing with them," she said.

Baroness Andrews was responding to a question from Baroness Seemombe who asked what action the Government was planning, following reports that UK nurses had concerns about inappropriate EHC supply by community pharmacists (*C&D*, May 3, p4).

RETAILING

Numark sees 58pc rise in rebate payments

Numark is claiming a record performance for the year 2001-2002, having paid out £9.67 million in rebates to members during the year.

The increase of 58 per cent on the £6.12m in rebates the previous year means that members have seen an average rebate of over £6,000 a year. Turnover has increased to a record £40.5m, with an operating profit before tax of £892,522, an increase of 243 per cent on 2001.

The news comes as Numark committed itself to implementing its Minimum Standards programme which should establish basic retailing standards with member pharmacies. Covering common areas of concern such as premises appearance and internal presentation of the pharmacy, the standards will be managed by the newly formed Retail Standards and Advisory Board. This comprises the chairmen – all of whom are pharmacy owners – of the regional committees and will have direct links into the restructured board.

The RSAB will seek to “identify, assess and adjudicate on

the pharmacies in need of help in achieving the basic standards, as well as provide guidance on any issues raised due to changes within the sector”, said Numark.

As part of the drive to improve support for members and to provide better communication between the company’s central office and members, Numark is building a team of business development managers. The first have been appointed to cover Scotland, the North of England, and the East Midlands and South Yorkshire regions. Others will be appointed over the next few months, and the country will be covered by 10 BDMS by October.

The appointment of BDMS follows the successful pilot in the Midlands area. Early data indicates that following the appointment of the BDMS there has been an initial 38 per cent increase in support for Numark and NTL programmes.

Commenting on the activity, newly-titled chief executive David Wood, formerly managing director, said that the past year had been a significant one for the company and it showed the business plan can be delivered.

David Wood, Numark chief executive, sees 2001-2002 as a key year for the company, in which it delivered results to both members and shareholders



“The question was if we worked as a Plc, would we continue to deliver the benefits to members,” he said. “This shows we can deliver, both to the shareholders and members. The business plan is not to the detriment of members. We have increased what we provide to them.”

Referring to the minimum standards initiative, Mr Wood said the company has been considering minimum standards with members for years. “We believe it’s important that we seek to improve the standards within the Numark group,” he said. “We are focusing on the bottom 5 per cent

of members, those that really need some help, on a proactive basis, helping them to improve rather than be dictatorial.

“We see it as important and we are the first group to address the minimum standards issue. Yes, there could be fallout, but we believe that it would be better for the group as a whole to have recognised standards.

“Everybody recognises that if a member is not prepared to improve they can be removed, but we are starting with the carrot. It’s peer review, it’s their fellow pharmacists saying ‘maybe you could improve your standards’.”

FINANCE

New Partnership Funds available

The DTI is encouraging small businesses and manufacturers to apply for the next round of the Government’s £3 million Partnership Fund to be spent over the next three years.

The Partnership Fund provides support for companies to develop projects between employees and employers, often through a union, to improve communications and

solve problems in the workplace. To date, the fund has sponsored around 160 projects and distributed just over £5m to develop best practice.

Employment relations minister Alan Johnson said: “Partnership at work is essential to attract good staff and improve productivity. It’s all about employers and employees working together to solve business

problems and avoid some arising in the first place.”

Partnership Fund winners can receive up to a maximum of £50,000 from the DTI. The winners come from the private, public and voluntary sectors and from both unionised and non-unionised organisations.

For more information:

www.dti.gov.uk/partnershipfund

INDUSTRY

Xenova cuts jobs as drug trial suspended

Xenova, which has sites in Slough and Cambridge, has announced immediate plans to cut jobs in a bid to reduce operating costs after trial of its cancer drug tariquidar was suspended by its Canadian partner QLT.

This follows a recommendation by the Independent Data Safety Monitoring Committee which completed the un-blinded interim

review of the data for the two ongoing trials in this indication. The Phase 2b trial for tariquidar in chemorefractory breast cancer is unaffected and will continue.

QLT’s clinical development team will now be un-blinded so they can review all of the data and make informed decisions about plans for the future development of tariquidar.

David Oxlade, Xenova chief executive, said: “Xenova continues to believe that tariquidar has potential as an MDR modulator in cancer. We will explore further development opportunities once the un-blinded data from these NSCLC studies have been assessed.

For more information:

www.xenova.co.uk

INDUSTRY

Pfizer shuts Pharmacia’s R&D centre

Pfizer is closing Pharmacia’s drug development centre in High Wycombe with the loss of 164 jobs as it begins combining operations under the Pfizer name following its £36 billion merger with Pharmacia (C&D, April 19, p9).

This closure is part of a global rationalisation which Pfizer says is an attempt to improve the efficiency of its R&D. It will transfer some jobs to its European R&D headquarters in Sandwich, which is itself cutting 200 jobs.

However, Pfizer said it will create 1,000 jobs at its Manhattan premises in the next year and spend approximately £250 million to acquire a Manhattan office building and renovate Pfizer premises in New York.

For more information:

www.pfizer.com

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PRESENTATIONS: Film-coated tablets containing 10mg cetirizine hydrochloride. **USES:** Treatment of seasonal and perennial rhinitis and chronic idiopathic urticaria. **DOSAGE AND ADMINISTRATION:** Adults and children aged 6 years and over: 10 mg daily. Children between 6 to 12 years of age: either 5mg (1/2 tablet) twice daily or 10mg once daily. In renal insufficiency halve the dose to 5 mg (1/2 tablet) daily. Zirtek Allergy Relief: Adults and Children aged 12 years and over: 10mg once daily. **CONTRAINDICATIONS:** Hypersensitivity to the constituents, lactation. **INTERACTIONS:** To date there are no known interactions. As with other antihistamines avoid excessive alcohol consumption. **SIDE EFFECTS:** Mild and transient drowsiness, headache, dizziness, agitation, dry mouth and gastrointestinal discomfort. Convulsions have very rarely been reported. **USE IN PREGNANCY:** As with other drugs, the use of cetirizine in pregnancy should be avoided. **PACKAGING/PRICE:** Zirtek Allergy: Pack of 14 tablets = £7.95 R.R.P. Pack of 30 tablets = £14.95 R.R.P. Zirtek Allergy Relief: Pack of 7 tablets = £4.45 R.R.P. **LEGAL CATEGORY:** Zirtek Allergy: P. Zirtek Allergy Relief: GSL. **MARKETING AUTHORISATION NUMBER:** PL 08972/0032 **MARKETED BY:** UCB Pharma Limited, Watford, Herts, WD18 0UH. **ZIRTEK ALLERGY SOLUTION** **PRESENTATIONS:** Banana flavoured sugar-free solution containing 1mg/ml cetirizine hydrochloride **USES:** Treatment of seasonal allergic rhinitis in children aged 2 years and over, and perennial

allergic rhinitis and chronic idiopathic urticaria in children aged 6 years and over. **DOSAGE AND ADMINISTRATION:** Adults and children aged 12 years and over: Two 5ml spoonfuls once daily. Children aged 6 to 11 years of age: Two 5ml spoonfuls once daily or one 5ml twice daily. Children between 2 to 5 years of age: One 5ml spoonful once daily or one 2.5ml spoonful twice daily. **CONTRAINDICATIONS:** Hypersensitivity to the Constituents, Lactation. **INTERACTIONS:** To date there are no known interactions. As with other antihistamines avoid excessive alcohol consumption. **SIDE EFFECTS:** Mild and transient drowsiness, headache, dizziness, agitation, dry mouth and gastrointestinal discomfort. Convulsions have very rarely been reported. **USE IN PREGNANCY:** As with other drugs, the use of cetirizine in pregnancy should be avoided. **PACKAGING/PRICE:** 75ml Solution = £5.99 R.R.P. **LEGAL CATEGORY:** P. **MARKETING AUTHORISATION NUMBER:** PL 08972/0033 **MARKETED BY:** UCB Pharma Limited, Watford, Herts, WD18 0UH. For further information please contact: UCB Pharma Limited, UCB House, 3 George Street, Watford, Herts, WD18 0UH. Telephone (01923) 211811. Facsimile (01923) 229002. Date of preparation: February 2003. UCB-ZA-03-02

References:

1. IMS HEALTH MIDAS data. Units sold from July 2001 - June 2002



PI traders win licensing battle

Parallel trade versions of a drug can continue even in the absence of marketing approval for the same domestic form, the European Court of Justice has ruled.

In a boost for PI traders, the Court has ruled that when a marketing authorisation for a medicinal product of reference is withdrawn at the request of the holder for reasons other than the protection of public health, there does not appear to be any reason to justify the automatic cessation of the corresponding parallel import licence.

The ruling followed a decision by the Swedish and Finnish marketing companies of Astra



The European Court of Justice ruled there is no reason to withdraw a parallel import licence if the original marketing authorisation is withdrawn for reasons other than those of health

(now Astra Zeneca) to withdraw Losec (omeprazole) capsules, cancel the relevant marketing authorisations and refocus promotional efforts on Losec MUPS, the dispersible tablet version. Explaining its decision, the Court said that the withdrawal of a marketing authorisation does not mean in itself that the quality,

efficacy and safety of the old version is called into question.

Commenting, Erik Pfeiffer, chief executive of Paranova, Astra's local marketing group, said: "This is a victory for patients... who will have the option of continuing to take a known product, supplied through national trade."

Euro biotechs surf 'success wave'

A "potential tidal wave of product successes" is building up in the European biotech industry, despite the current harsh business environment.

According to the latest Ernst & Young Endurance report, Europe's public biotech companies now have 53 products in phase 3 clinical trials.

However, cash constraints in what is a predominantly UK-based industry could hamper success, analysts warn.

Ernst & Young notes that a decade of between 30-40 per cent revenue growth has now gone into reverse and for the first time in the industry's history, in 2002 total revenue fell by 2 per cent to €12.9 billion. Between 2000 and

2002, venture capital investment in the sector also fell 82 per cent to €1.2bn.

According to analysts, cash constraints, coupled with political and economic uncertainty, are forcing companies into binding, potentially cash-depleting transactions and programmes of cost-cutting and withdrawal from non-core activities.

However, as much as 300 per cent growth could be on the cards, when the current down cycle ends, report lead author Glenn Crocker said.

Around 45 per cent of public biotech companies are located in the UK, accounting for 43 per cent of market capitalisation.

● Some 16 medicines to overcome

schizophrenia are in different stages of development, according to a new report from the ABPI called *Target Schizophrenia*.

The report examines the huge cost of schizophrenia to society. Estimates suggest that the total cost is £23,000 per patient per year, adding up to a total annual sum including lost productivity of £2.7 billion. Of this, medicines account for less than five per cent.

Copies of *Target Schizophrenia*, are available free from the Publications Department, ABPI, 12 Whitehall, London, SW1A 2DY; tel 020 7930 3477 ext.146; fax 020 7747 1411; or e-mail: publications@abpi.org.uk.

LOGISTICS

Making the chain work

The Institute of Logistics & Transport is holding its convention and exhibition at Birmingham's International Convention Centre from June 17-18 with part of the programme dedicated to pharmaceutical/healthcare logistics. Chaired by Mike Owen, director of communications at the Proprietary Association of Great Britain, speakers include Barry Mellor from the NHS Logistics Authority and Cliff Bull from Pfizer Consumer Healthcare.

For more information:

www.ilt2003.co.uk Tel: 01895 454411.

Coming Events

MAY 20 Ipswich & Suffolk Branch, RPSGB

A Charter Fit for the Future, by Christine Gray, RPSGB modernisation programme manager, at the Cedars Hotel, Stowmarket, 7.30 for 8pm.

MAY 21 West Metropolitan Branch, RPSGB

AGM followed by *Diabetes - delivering the NSF*, by Dr Anne Dornhorst, consultant diabetologist, Charing Cross Hospital, at the lecture theatre, Post Graduate Medical Centre, Charing Cross Hospital, Fulham Palace Road, London W6 8RF, 6.30 for 7.30pm.

MAY 22 Weald of Kent Branch, RPSGB

Can I take alcohol? by John F Smith, MRPharmS at the Ramada Jarvis Hotel, Pembury, 7.30 for 8.15pm.

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lignocaine or other ingredients. Do not use on broken or infected skin. To be used externally on anal area only. Warnings and Precautions: The spray should not be used continuously for longer than seven days. Keep away from eyes, nose and mouth. Patients should seek medical advice if persistent pain or bleeding from anus occurs especially if associated with a change in bowel habit, a distended stomach or weight loss. Medical supervision is required if used in conjunction with other medicines containing

steroids. Side Effects: Temporary tingling sensation may be experienced. Rarely, hypersensitivity to lignocaine has been reported. Use in Pregnancy: There is inadequate evidence of safety in human pregnancy. Cost: 30 ml tube, £6.99. MA Number: PL 0173/0049. MA Holder: Dermal Laboratories, Gosmore, Hertfordshire SG4 7QR. Sold and Distributed in the UK by: Bayer plc, Consumer Care Division, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA. Legal Category: P. Date of Preparation: April 2002.



Comment

from the Editor

Presentation does matter, whether it is how you convey information to a patient or fellow health professional or whether it is the setting in which healthcare is delivered. What is said is only part of how a message is perceived.

For some parts of community pharmacy there is a dilemma. The excellent services that are being provided, particularly in deprived areas, are not being recognised fully for their worth because the premises from which they are offered do not indicate professionalism. So it is of significance that Numark is to start tackling the issue of raising standards in those 'bottom' 5 per cent of pharmacies where the premises are affecting business and giving the profession a bad name. While it wants to use a carrot rather than stick approach, Numark has indicated it is prepared to remove its franchise from those members who will not improve.

Numark is taking a bold step but it should reap benefits for the profession as a whole. Is it something that the new Charter should address? After all, 14 out of the 18 candidates standing for Council this year agreed that RPSGB inspectors should be given more powers to improve the

standards of pharmacy premises (*C&D April 19, p34*).

Another issue raising concerns is the extent to which the proposed new Charter deals with devolution. The draft Charter proposes the Society shall have power "by regulation to establish, dissolve and regulate any form of geographical or other subdivision of the Society". This makes a change from the 1953 Supplemental Charter which says there shall be a Scottish Department of the Society (but not Welsh).

With healthcare devolved by government, it seems appropriate that there should be parts of the Society to deal with 'local' health matters. Is the fear justified, though, that by only referring to regions generically, pharmacists in Scotland and Wales could later be disenfranchised?

Another issue raising concerns is the extent to which the proposed new Charter deals with devolution

Your views

Mark Gibson from Schering Health Care talks about the MS risk drugs sharing scheme

Great idea if we can only make it work

The Department of Health's risk sharing scheme for MS drugs now has a mountain to climb to meet the target of providing 9,000 MS patients with access to disease modifying therapies by this November.

The scheme is an innovative idea. It provides qualifying patients with MS drugs while also gathering data to ensure cost effectiveness. It has the potential to haul the UK out of the Dark Ages in terms of how the UK matches up to international standards of MS treatment.

But last week came depressing signs. The MS Society pointed to a huge backlog of yet-to-be assessed patients and predicted that treatment targets would not be met. It went on to name MS centres it said were failing to get sufficient numbers of patients through the system.

More bad news came from



Mark Gibson:
only conviction plus optimism could see the MS scheme delivered in time

Liberal Democrat MP Paul Burstow. He suggested that only 20 per cent of people eligible for the drugs had been able to get them. He claimed government ministers sold false hopes to people with MS when the scheme was announced in February 2002. That's borne out by Haley Jackson from Cornwall, who still can't get access to MS drugs locally. She highlights the

personal cost of delay, declaring: "The situation here is terrible, if the scheme were running when I was diagnosed I might not have the severity of the illness I have now."

So with patient groups, politicians and pharma companies all expressing doubts about the November targets, it was only the DoH that said it still expects the original assessment and prescribing goals to be met. I want to share their optimism. For the sake of MS patients this scheme deserves to work.

It's good news that things are speeding up. With the new financial year, budget is being made more widely available for treatments provided under the scheme. At Schering we are pleased to support the recruitment and training of more MS nurses. And patient groups are active in highlighting

problems. Armed with intelligence about poorly performing centres, local stakeholders can more effectively deal with specific local issues.

But the big lesson is not to underestimate the amount of effort needed to push this kind of national healthcare initiative through at a local level. Central co-ordination needs to be more hands-on. Communication needs to be more regular, giving clarity around expectations and a means of sharing ideas. Progress has to be monitored closely so problems can be identified and resolved quickly. And finally, even if you do place NHS Trusts and clinicians under a duty to provide, don't expect the job of selling-in the initiative to end there.

Only conviction plus optimism could still see the scheme in with a chance of delivering by November or soon after.

INDUSTRY VIEWPOINT

Is the price right?

It is now two years since the demise of resale price maintenance on OTC medicines. There were dire predictions of the consequences but the reality has proved to be somewhat different. Multiple grocers are taking more of the market but that trend was already underway and there have been few, if any, pharmacy closures that can be attributed to the demise of RPM.

A review of the current situation shows a very mixed approach to pricing. Most promotions and price reductions target GSLs but P medicines have been involved. In some cases manufacturers are fully or part funding the reductions but retailers are foregoing some of their margin. The majority of independent pharmacies have implemented manufacturers' recommended prices while the national multiples slug it out in an attempt to gain share.

Asda is committed to "everyday low pricing", as is Tesco. Sainsbury's main approach is price promotions but its ongoing prices

Medicines are an infrequent purchase... and price does not drive additional consumption

are generally above EDLP. Sainsbury's has slashed prices on selected SKUs for a limited period, resulting in significant volume increases.

Boots has mainly stuck with its buy one get one free or three for two approach. It has also implemented a number of 99p offers on certain key lines.

Lower prices and promotions do produce additional volume but much of this is short term and the total OTC market remains sluggish. Medicines are an infrequent purchase, mainly bought against symptoms and price does not drive additional consumption. People remember product quality and service long after they have forgotten the price.

Written by a senior industry manager

TOPICAL REFLECTIONS

Three cheers for a rural pharmacy success story

In my years of wandering through the English countryside I have witnessed the slow destruction of rural village services, an apparently inexorable slide into extinction of small businesses unable to compete with larger rivals in the towns.

The rise of the superstore, better roads and increased affluence have all contributed to this regrettable decline so I was particularly pleased to read in the pages of the *Sun* (Wed May 7) of a village business that has bucked the trend. I was even more pleased when I realised it was a pharmacy I know in the Northamptonshire village of Earls Barton.

The good citizens of this village have a successful local pharmacy that provides a diversity of services that now, after six local banks and building society branches closed down, also includes a thriving building society agency.

I have seen the Aladdin's cave of a pharmacy owned by David and Georgina Jeyes and to the professional purists it may not be ideal. But it is successful, maintains essential services and provides a rural community with a pharmaceutical service that might have otherwise been destroyed. What makes it all the more enjoyable is that this is a nationally reported success story.

Have a heart Roche, your INR meters are too dear

Having effectively dominated the market for the home testing of blood glucose by diabetics, Roche Diagnostics is now turning its attention to those patients on warfarin who have to monitor their INR (International Normalised Ratio). The sticks for their CoaguChek S meter are available on prescription but as usual the meter has to be purchased. Now buying a meter is rarely a problem for diabetics as the prices are at an all-time competitive low, but at £399 for the CoaguChek S

those of my patients who are interested soon change their minds. It may be more convenient but *not that* more convenient is the unanimous response.

Roche may be happy with its present sales but for the market to really take off the capital price of the meters must be reduced. At the moment Roche has an effective monopoly. If I were its marketing manager I would reduce the meters to an acceptable cost and maintain my lead in what could become a highly lucrative market.

Can PSNC pull the rabbit out of the hat?



Open shop (C & D May 10, p16) made for depressing reading because Alan Castell highlighted the black hole of financial despair that could soon engulf many community pharmacists. To the question, why should the Department of Health be concerned, the answer has to be that at the moment it is not. While large multiples are willing and able to make overall profit on their pharmacy activities and while the smaller players are prepared to absorb decreasing returns as the alternative to total oblivion then the DoH will see no reason for directly increasing the resources allocated to the pharmacy contract.

Any new contract will be funded by a combination of the redistribution of the existing global sum and the opportunity to convince each individual primary care trust that in the interest of the overall provision of primary healthcare services, they should increase their resources applied to community pharmacy. Now bearing in mind that presently most PCTs fund few, if any, recurring extra contractual services by community pharmacists, the probability of these organisations rapidly embracing the new order and enthusiastically organising medication management schemes, supplementary prescribing or patient group directions is indeed remote. Perhaps PSNC will pull the proverbial rabbit out of the hat and by this time next year defined opportunities for pharmacists will have become national policy but I doubt it. I remain optimistic of my professional ability to deliver improved services but the statistical time bomb of financial disaster identified by Mr Castell will probably explode before the DoH accepts the error of its ways.

Make your voice heard

Graham Philips explains why he believes you should attend the SGM on June 1



Largely as the result of appalling acts such as the Shipman murders and the Bristol Royal Infirmary children's heart surgery enquiries, public faith in the health professions and the NHS has been severely undermined.

The Government's resolution of this crisis lies in its response to the Kennedy Report, which sets out 13 crucial roles that must be undertaken by a 'modern regulator.' All the professions must satisfy these criteria or lose their right to self-regulation. An over-arching body, the Council for the Regulation of Health Care Professionals (CRHP), will oversee the regulatory bodies for health professions. Should the pharmacy profession (in common with every other

profession) not satisfy the CRHP, there is a real risk that we will lose our right to self-regulate and that the Government will assume direct control over pharmacy regulation.

Responding to this, Council established the Modernisation Steering Group (MSG) to bring forward proposals about pharmacy professional self-regulation, the reform of disciplinary procedures and

changes to the structure of the Council itself.

So far, the Council has agreed:

- to reform the Council, reducing the number of elected pharmacists from the current number of 21 to 17;
- to increase the number of lay representatives (in point of fact, unelected government nominees) from three to 10;
- to become the registration authority for dispensing technicians and afford them two places on Council;
- to seek a new Royal Charter;
- to turn the Society into a charitable organisation.

Uniquely, the Society combines the functions of professional representation and regulator. And one of the objects within the Society's current Charter is "to maintain the honour and safeguard and promote the interests of the members in their exercise of the profession of pharmacy".

Beyond the membership fees, the Society enjoys considerable additional income from non-regulatory roles, especially from publishing. The concern of many is that the Society is being transformed by stealth into solely a regulatory body, leaving pharmacists with no official body to represent their interests. Worse still, the income from the non-regulatory functions, together with the assets built up by the profession over the years, are at risk of being applied to the regulatory role.

The Society as currently constituted meets all but one of the 13 roles proposed by the Kennedy Report, the

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exception being revalidation (which is anyway in hand). The Young Pharmacists' Group proposes an alternative model in which the Council would continue at its current size and constitution and would take an over-arching role. It would operate through a series of committees, with an emphasis on representing and leading the profession.

In order to satisfy the regulatory requirements, a Pharmacy Regulation and Compliance Committee (PRCC) would be constituted. This would deal with registration, professional rules, compliance with rules and standards and referrals to the Statutory Committee.

The Statutory Committee itself requires little reform as it is already recognised as best practice. It would retain a chair with judicial experience, and a membership of three pharmacists plus two lay members.

The YPG proposals have a great deal to recommend them. The public interest (regulation) would be fully served and, at the same time, the representative role strengthened.

But consider some of the current major issues facing pharmacy. Should the Council's proposals be enacted, how could the Society possibly represent the conflicting interests of both pharmacists and technicians? How would the Society deal with the current Office of Fair Trading report? How would the Society be able to raise issues such as the desperate

shortage of pharmacists in secondary care? These examples demonstrate why it is essential to maintain the Society's strong and independent representative function.

To make changes to the current Royal Charter requires a 75 per cent majority in a Council vote, plus a 75 per cent majority of members at a special general meeting. I believe the Society would not gain the required majority, so its proposal for a new Charter

"Pharmacists uniquely among the professions have no representative body"

sidesteps this democratic obligation.

Is the proposal for a new Charter necessarily a bad idea? No. The old Charter has probably outlived its usefulness and the introduction of a new one represents a golden opportunity to re-establish the Society clearly and decisively with its dual roles in representing and regulating the profession. However, the proposed new Charter removes the essential commitment to represent the profession.

One of the current Charter objects is to: "Maintain the honour and safeguard and promote the interests of the members in their exercise of the profession of pharmacy". Significantly, there is no equivalent object in the proposed new Charter.

Charities can only act in the public interest,

whereas the Society has a dual role. By becoming a charity, the Society greatly restricts any chance of representing the profession, especially important where the Government is making manifold and often unreasonable demands on all the professions.

Pharmacists uniquely among the professions have no representative body. Community pharmacy owners do at least have the NPA and PSNC, but this leaves all employee

community pharmacists, including self-employed locums and pharmacists in industry and hospital employment, totally unrepresented unless they join an appropriate trade union. Given the notoriously low morale within the profession and the appalling

shortage of pharmacists, especially in the secondary care sector, this would be a disaster for us.

The MSG has been criticised from the start because it seems set on a pre-determined path, although the Society's modernisation website suggests around 95 per cent of the 1,932 pharmacists who responded to the consultation oppose the proposals!

The SGM on June 1 provides us, the members, with an important opportunity to stop this before it goes too far. It is vital that pharmacists attend en masse to make their voices heard. A good turn-out on the day with strong support for the two motions will be heard not only in Lambeth but also in Whitehall. ☺

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*Reference: Hadgraft J, et al (2003) Skin Penetration of Topical Formulations of Ibuprofen 5%: An in vitro Comparative Study. Skin Pharmacology and applied Skin Physiology Vol 16, No3. 137-142.

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Side-effects: In normal use, side-effects are very rare, but may occasionally include allergic or localised skin reactions in susceptible individuals.

Legal Category: P Packs: Gel (PL0173/0060) - 30g, RSP £3.89 (£3.31 exc. VAT) and 50g, RSP £5.39 (£4.59 exc. VAT).

Pharmacy consultant Richard King visited France's leading pharmacy trade show recently, and was pleasantly impressed...

For those who have never ventured across the Channel to a European pharmacy show, attending Pharmagora in France is a really positive, buzzing experience.

European pharmacy shows are so successful primarily because restricted pharmacy ownership rules in most of Europe, which mean that the proportion of pharmacists who are also pharmacy proprietors is much higher than in the UK. Most proprietors are naturally more motivated to seek ideas to develop their businesses than their employees.

This year's Pharmagora Exhibiton was held in Paris at the Paris Expo Porte de Versailles Exhibition Centre on March 22-24. Just under 500 exhibitors were spread throughout one massive aircraft hanger-sized hall. They were primarily from France and covered every kind of pharmacy-related product and service. There were, for example:

- 10 generics companies (a relatively new sector in France);
- 14 software companies;
- 26 shopfitters/robotics suppliers (three of whom supply in UK);
- 15 sun protection companies;
- four smoking cessation suppliers (including GSK and Pharmacia);
- legions of buying groups of all types and sizes.

Additionally, over the three exhibition days, over 100 lectures and seminars were run in various rooms off the main hall.



The IT angle

It is not a requirement in France to label dispensed medicine packs, and patient packs have been the norm for over 25 years. Patients follow the pack information leaflet for dosage, unless an unusual dosage regimen is specified, in which case the pharmacist writes it on the pack.

The raison d'être of French software suppliers, most of whom were at the show, is to focus on helping pharmacists deal effectively and efficiently with the immensely complex French payment model for prescription reimbursement. One such company, IsiPharm, was at the show demonstrating software which interfaces with patients smart



The Government has given a commitment to commission research and development in the NHS, and has emphasised the need for all staff to be involved in developing innovative ways of improving patient care. Few pharmacists currently read research papers, undertake research or use it to change their everyday practice. The Day Conference is designed to encourage practising pharmacists to engage in these activities

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Narcotics tests

One company was attracting special attention with its launch of a testing product that can detect minute traces of cannabis, opiates, cocaine and amphetamines, either on the skin, in urine or even on work surfaces. Four test strips are held in a special holder with a removable protective cap. The strips are wiped against the suspect fluid or surface. Three drops of water are added and the cap replaced. After two to three minutes nanogram/ml levels of the four drug classes can be detected.

cards. The French have now given every adult a smart card which carries the patient's basic details, including the insurer who covers the cost of their healthcare (including prescriptions). The patient can hand the card in to any doctor or pharmacy of their choice, and when the card is placed in a secure card reader, together with an encrypted card held by the doctor/pharmacist, this facilitates rapid data exchange, resulting in payment within five days for the healthcare professional.

Other interesting software developments seen or under development included:

- software that would build planograms for an individual pharmacy based upon sales data from the shop's EPoS system;
- software that would highlight associated sales opportunities based upon prescription information;
- software (running on a PDA) that would allow sales representatives to take and place orders, check stocks, report their visits and sales statistics, and then by connecting the PDA to a mobile or land telephone line to communicate with a central server for online data exchange.

Buying groups

Because most pharmacies are independently owned, France has a long history of what we would call buying groups – they call them groupements. One such, Alrheas, has committed all its members to multiple computer flat-screen displays in its pharmacies to promote the retail product offers that are available to the group's customers and advertised nationally on TV.

Other groups focus on improving the member's pharmacy appearance, own-label medicines provision and assistance with new market development, marketing, merchandising, price guidance and so on. Groups are often regionally based, but some appeal nationally, for example PlusPharmacie, which claims to have primarily high turnover pharmacies in membership.

Generics sector

The French generics market is still at a fairly embryonic stage. GPs showed no interest in writing prescriptions generically when asked by the government to do so. Pharmacists, therefore, face the unenviable task of voluntary substitution against considerable consumer suspicion and resistance.

It is clear to generics manufacturers that the French market, given patience, has huge potential, and new suppliers are entering the market now, to get in on the ground floor. Some of the major ethical branded manufacturers (Aventis and Merck) have set up French generic subsidiaries and were represented by stylish stands at the show. There were equally stylish stands from familiar generic specialists such as those we have trading in the UK such as Ivax and Teva.

Shopfitting and robotics

On the shop fitting and automation front, French pharmacists have always invested heavily in a high quality professional appearance for their pharmacies.

Twenty six well-established French, German and Swedish companies who supply and export excellent quality continental drawer and shelving systems were present at the show. Most of them are now working on automated/robotic dispensing picking machines, which, though expensive, may save time and space and thereby increase patient/pharmacist contact time in busy pharmacies.

Over 400 robotic systems are understood to have already been installed in Europe, compared to about three so far in the UK. German companies like Willach, ARX and Westfalia had some very elegantly engineered robotic solutions on display. ☺

Those interested in learning more about pharmacy in France might like to take a look at www.ordrepharmaciens.fr developed and supported by the L'Ordre des Pharmaciens



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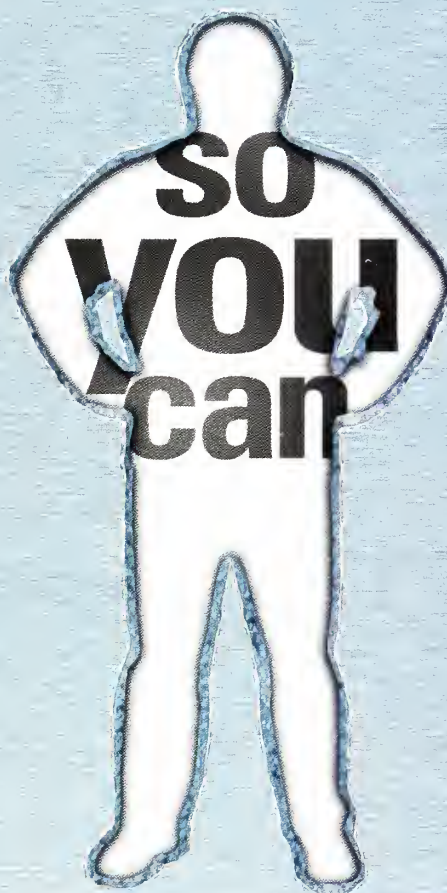
CoaguChek S

The concept of self-testing is supported by the Children's Heart Federation (CHF) and Anticoagulation Europe (ACE)

1. The expert patient. A new approach to chronic Disease Management for the 21st century log onto www.doh.uk/healthequality 2. Medicines and Healthcare products Regulatory Agency (MHRA) report. MDA 01026 Available free of charge to NHS employees log onto www.medical-devices.gov.uk 3. Preliminary data held by the MHRA



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Last week *Dr Mike Mead* looked at dietary intervention to prevent heart disease. Here he concentrates on the use of statins and other cholesterol lowering agents

Cholesterol busters



THE COLLEGE OF PHARMACY PRACTICE

This course (module 1271), in association with multiple choice questions being published in C&D June 7, provides one hour's continuing education

Objectives

- To know which patients should be treated
- To understand the benefits and risks of statins
- To know how to advise patients
- To know when statins are not the complete answer
- To be aware of new drug developments

There are three groups of patients to be considered when deciding whether and how to treat hypercholesterolaemia:

1. Patients with familial hypercholesterolaemia.

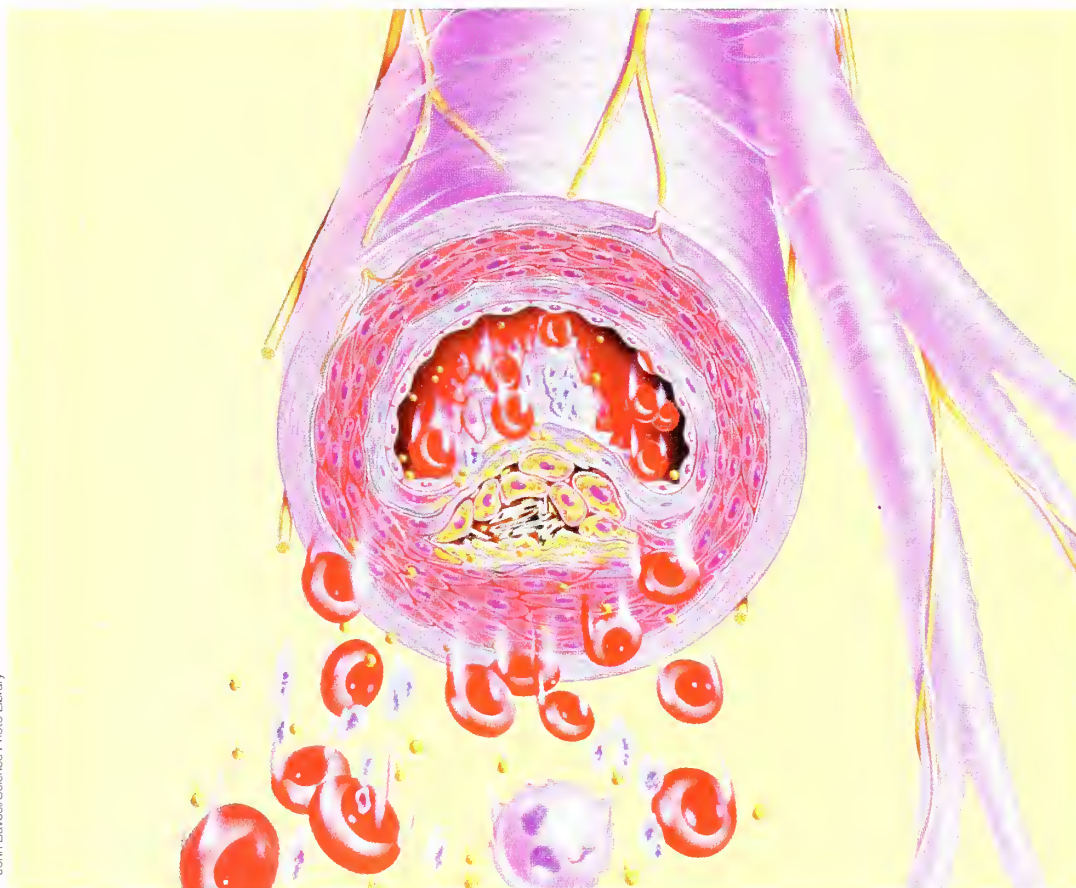
These patients have high total cholesterol (over 8mmol/l) and may have a family history of premature coronary heart disease (CHD), that is, CHD before age 55 years in males and before age 65 in females. The families need close monitoring and tend to be treated in special lipid clinics.

2. Patients with existing cardiovascular disease or diabetes.

These patients are at high risk from hypercholesterolaemia and views are changing on their management.

The recently reported Heart Protection Study¹ demonstrated clear benefit in treating patients at high risk of vascular events, such as patients with diabetes and those with a stroke or myocardial infarction, irrespective of cholesterol level. The entry cholesterol level for the Heart Protection Study was 3.5mmol/l and above, and benefit was shown even at these lower levels.

Current best evidence-based practice is therefore to give such patients a statin (the Heart Protection Study used 40mg of simvastatin), even at lower levels of total cholesterol. Before this study we were targeting patients with diabetes, cardiovascular disease or CHD to drop their total cholesterol below 5mmol/l and their LDL cholesterol below 3mmol/l.



Artwork showing a cross section through an artery narrowed by atherosclerosis

3. Primary prevention of cardiovascular disease.

We know from the West of Scotland Coronary Prevention Study² (WOSCOPS) that statins can be beneficial in the primary prevention of CHD.

In WOSCOPS men aged 45-64 with hypercholesterolaemia were treated with pravastatin 40mg daily and, as the LDL cholesterol was reduced by about a quarter, the number of coronary events

(including fatal cardiovascular events) was reduced by a third.

We know that statins, as well as protecting the patient from CHD, will provide a similar level of protection (reducing the risk by about a third) from stroke.

The decision on whether to treat patients without existing cardiovascular disease/diabetes/familial hypercholesterolaemia depends on their predicted 10-year CHD

risk. This can be determined easily with risk tables, as appear in the back of the *British National Formulary*, where you work out the patient's 10-year CHD risk based on age, sex, presence of diabetes, smoking habit and total HDL cholesterol ratio.

Because of cost considerations, there is a great deal of debate as to which level of risk justifies statin

Continued on page 22 ►

therapy. Just treating those with over a 30 per cent 10-year risk is not good practice and denies many patients substantial benefit.

Every primary care organisation should decide the levels of risk at which they will support statin therapy, not least to ensure consistency throughout the primary care trust. Once treating the patient, the target should be that defined by the National Service Framework for CHD,¹ that is, to lower serum cholesterol *either* to less than 5mmol/l (LDL-cholesterol to below 3mmol/l) *or* by 30 per cent (whichever is the greater).

Key messages

Statins work by inhibiting the enzyme HMG CoA synthetase, an enzyme involved in cholesterol synthesis, especially in the liver.

There are several important pieces of advice to give patients:

- Encourage dietary measures already being taken and the addressing of other risk factors like smoking and hypertension. You never treat hyperlipidaemia just in isolation – you need to treat it as one of a number of cardiovascular risk factors.

- Explain to the patient that this is a lifelong treatment to reduce risk – statins work continuously to lower cholesterol by inhibiting synthesis in the liver. The treatment should not be stopped, nor tablets missed. This is very important advice, as compliance with statin therapy is known to be poor. In a study of over 30,000 elderly patients on statins, for example, *Benner et al*² used the marker of proportion of days covered (PDC) by a statin (as the other phenomenon well known with statin use is missing tablets on some days).

The level of under 80 per cent PDC (that is, fewer than 80 per cent of days covered by a statin) increased from 40 per cent at three months to 61 per cent at a year after starting treatment. Only one patient in four maintained a PDC of at least 80 per cent after five years.

- Take your statin at night to achieve maximum effect (although atorvastatin can be given at any time of the day). Cholesterol production in the liver is highest in the evening, peaking around 10pm, but as atorvastatin has a relatively long duration of action this timing is less relevant.

- Advise the patient to report any new, unexplained muscle aches, tenderness, pains or weakness, as this may be related to statin use.

- There is evidence that



Diabetics will encounter particular risks and are usually best treated for cholesterol at the local lipid clinic

grapefruit juice, taken at the same time as simvastatin, can increase plasma levels of the drug.

It would be prudent at this stage also to check there are no contraindications to statin use, such as liver disease, pregnancy and lactation. With increasingly younger patients going on to statins, such as young diabetics, it is also important to remember that you need adequate contraception while using a statin and for one month afterwards. There is a possibility that statins have a teratogenic effect.

Side effects and monitoring

Statins are safe drugs with a low incidence of side effects at the doses generally used. The serious side effect of rhabdomyolysis is rare. This is a condition in which muscles break down and release cell contents into the blood stream. But there is an increased risk of myopathy if statins are

used with fibrates or nicotinic acid (at the high doses of 600mg or more used in hyperlipidaemias), or the patient has renal impairment or hypothyroidism.

Other side effects include headache, altered liver function tests, gastrointestinal side effects (nausea, dyspepsia, diarrhoea), insomnia and rash. Although we don't see side effects as an issue with the doses commonly used (such as simvastatin 20mg or 40mg), there is a greater incidence of side effects at the higher doses. Discontinuation rates for statins are about 5–10 per cent.

For monitoring purposes, liver function tests must be measured before starting the statin and repeated within three months. The liver function tests should be measured at six-monthly intervals for a year, then annually or three months after any change or increase in the statin dose. Statins should be discontinued if serum transaminase concentrations rise

to three times the upper limit of normal. This occurs in about 1 per cent of patients, again often at the higher doses. Patients are asymptomatic and the problem is usually reversible on discontinuing treatment.

In the future one would expect pharmacists to be involved more and more in advising on, and monitoring, statin therapy. There must be a good chance of statins, at least in lower doses, leaving POM status.

If muscle pain is reported the GP will do a serum creatine kinase to check for a myositis.

There are a couple of important drug interactions to remember. Erythromycin use with statins may increase the risk of myopathy and warfarin's effect is enhanced by simvastatin. A few less commonly used drugs, like itraconazole and ciclosporin, may also increase the risk of myopathy.

What statins do not do

Statins are very effective at lowering LDL cholesterol and huge numbers of patients will be starting on these drugs to reduce cardiovascular risk. What statins are less effective at is reducing triglycerides and raising HDL cholesterol. The combination of raised triglycerides and low HDL cholesterol is a particular cardiovascular risk in diabetes³ and here one may need to address the raised triglycerides/low HDL cholesterol with another drug. Fibrates are the obvious answer as these can lower triglycerides by 30–50 per cent and raise HDL cholesterol by 10–20 per cent.

However, the increased risk of muscle disorders with the combination of statin and fibrate means that patients requiring combination statin-fibrate therapy should really be under the care of the local lipid clinic. Adding Omacor to a statin, as discussed in the previous article, is an alternative to using a fibrate in this situation to lower triglycerides.

A new class of drugs

The management of patients with hypercholesterolaemia is about to undergo a significant change with the arrival of a new class of cholesterol lowering drugs, called the selective cholesterol absorption inhibitors (SCAIs).

The first of this new class of drugs, ezetimibe (Ezetrol), has just arrived in the UK (C&D

Continued on page 24 ►



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Reference: 1. IMS June 2002 2. IMS March 2003

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Presentations: Eye Drops containing Sodium Cromoglycate 2% w/v **Indications:** Relief and treatment of seasonal and perennial allergic conjunctivitis. **Dosage & Administration** (including the elderly): One or two drops in each eye up to four times a day or as indicated by a doctor. **Contraindications:** Hypersensitivity to ingredients. **Precautions and Warnings:** Product is unsuitable for use with soft contact lenses. **Pregnancy:** Caution should be advised during 1st trimester of pregnancy. Although experience with sodium cromoglycate suggests that it has no effect on foetal development, it should be used only when there is a clear need. **Adverse Effects:** Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported rarely. **Legal Category:** P **Pharmaceutical Precautions:** Store below 30°C and protect from direct sunlight. Discard any remaining contents 4 weeks after opening. **Retail Price:** Eye Drops 5ml – £4.09. PL No 04425/0323 Eye Drops 10ml – £5.09. PL No 04425/0323 **Date of Preparation:** April 2003.

Further information is available from Aventis Pharma Ltd. 50 Kings Hill Avenue, Kings Hill, West Malling, Kent ME19 4AH, United Kingdom.

April 26, p 21). Ezetimibe[®] acts by selectively inhibiting the intestinal absorption of dietary and biliary cholesterol by reducing the absorption of cholesterol across the brush border of the intestinal wall. It does not alter the absorption of triglycerides, fatty acids, biliary acids or fat-soluble vitamins (and is hence different from the bile acid sequestrants like colestyramine[®]). This is, of course, a completely different mode of action from the statins and the two types of drug can be used together.

So ezetimibe will be particularly useful in achieving target levels of cholesterol reduction when combined with existing statin therapy, obviating the need to push statin therapy higher with the risk of side effects noted above.

In a study adding ezetimibe 10mg daily (the standard dose) to other statin monotherapy, ezetimibe resulted in an additional LDL cholesterol reduction of 25.1 per cent compared with 3.7 per cent additional reduction with placebo.⁷

The addition of ezetimibe also increased HDL cholesterol by more than placebo (2.7 per cent compared with 1 per cent) and decreased triglycerides by 14 per cent compared with a 2.9 per cent decrease with placebo.

There was no evidence of adverse effects in combining ezetimibe with a statin and no increase in muscle-related adverse events. Ezetimibe has no significant side effects: combining ezetimibe with a statin doesn't increase the rhabdomyolysis risk.

Cost consideration

Trying to gauge the cost-effectiveness of particular statins is difficult because:

- They are not equipotent at similar doses. Fluvastatin 20mg is less than half as potent, for example, as atorvastatin 10mg or simvastatin 20mg at lowering LDL cholesterol. You are much more likely to need fluvastatin 80mg daily than 80mg of simvastatin or atorvastatin.

- Not all statin effects are due to cholesterol lowering – they have other effects, such as antithrombotic or actions at the endothelial wall – and to achieve the reduction in cardiovascular events we need to use the doses used in clinical trials, that is, 20mg simvastatin (Scandinavian Simvastatin Survival Study), 40mg simvastatin (Heart Protection Study) and 40mg pravastatin (WOSCOPs and the CARE study on secondary prevention after a myocardial infarction). These are the big outcome studies and the cost of these doses of statin are all the same (£29.69 for 28).

- The whole cost issue will shortly change as simvastatin has come off patent this month. Many are already anticipating this cost change.

Rosuvastatin recently entered the market against stiff competition from other statins with robust safety and efficacy data. Only time will tell whether the evidence base in reducing CHD will be as strong for the new drug.

Summary

The statins are major drugs in our armamentarium to reduce cardiovascular disease. As with all

drugs they need to be used rationally, effectively and with a programme of monitoring and patient education to ensure they achieve their required result. Pharmacists can play a key role here, not least in ensuring compliance.

References:

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3. National Service Framework: Coronary Heart Disease. Department of Health 2000.
4. Benner JS, Glynn R, Mogun H et al. Long-term persistence in use of statin therapy in elderly patients. *JAMA* 2002; 288: 455-461.
5. Mead M. Targeting lipids in diabetes. Update, 16 May 2002, 618-628.
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7. Gagne C, Bays HE, Weiss SR et al. Efficacy and safety of ezetimibe added to ongoing statin therapy for treatment of patients with primary hypercholesterolaemia. *Am J Cardiol* 2002; 90: 1084-1091.

Dr Mike Mead, a full-time GP in Leicester, is adviser to many medical journals, author of medical books and lecturer in medical matters in the UK and overseas. He is on the Healthcare Advisory Panel of the Blood Pressure Association, and chairman of the ASSET group, which is dedicated to education and training on strokes.

Actionplan

1. Revise your knowledge of serum levels of high and low density lipoprotein cholesterol. List target levels as a table in your practice workbook.
2. In your practice workbook list foods that are high in saturated fats. Also list foods that are beneficial (or at least neutral) in reducing total serum cholesterol. Using reference sources, try to devise a list of maximum intake of the "bad" foods to be eaten in any one week (for example, some sources say not more than two eggs a week).
3. Make sure you understand and can use the graphs shown in the back of the BNF relating coronary risk to various parameters.
4. Devise a questionnaire that would identify specific coronary heart disease risk for a particular client. Consider what advice you would give to a client asking about his or her own risk. Write the questionnaire in your practice notebook.
5. What are your views on the idea of making some statins P medicines? Discuss this with colleagues. Would such a change benefit the exchequer and/or the public?
6. Read the introduction to section 2.12 of the BNF.



There is evidence that grapefruit juice, taken at the same time as simvastatin, can increase plasma levels of the drug

Distance learning for pharmacists

Pharmacists using **Pharmacy Update** for continuing education are reminded of the need to test. With the support of Genus Pharmaceuticals, C&D's readers can self-test their progress by using the multiple choice question (MCQ) paper to be inserted in the June 7 issue, which will cover this week's CPP-accredited modules, together with those in the May 3 and 10 issues. These will cover:

● Foetal/child development (1269) ● Diet and CHD part 1 (1270) ● Diet and CHD part 2 (1271).

A telephone marking service offers independent verification of results – details on the monthly MCQ papers. People wishing to register for Pharmacy Update can contact Mary Prebble on 01732 377269.

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BENADRYL ALLERGY RELIEF Presentation: Acrivastine 8 mg. Uses: Allergic rhinitis. Dosage (12 - 65 years): One capsule up to 3 times a day. Contra-indications: Hypersensitivity to acrivastine or triprolidine or significant renal impairment. Precautions: It is usual to advise patients not to undertake tasks requiring mental alertness whilst under the influence of alcohol or other CNS depressants. Pregnancy & Lactation: Not recommended. Side effects: Rarely, drowsiness. Price: 12s £ 4.35 (£3.70 ex-VAT), 24s £7.55 (£6.43 ex-VAT). Legal category: P. PL Holder: Warner Lambert Consumer Healthcare, Eastleigh, SO53 3ZD. PL no: 15513/0035. Date of preparation: April 01. **BENADRYL PLUS CAPSULES** Presentation: Acrivastine 8mg and pseudoephedrine 60mg. Uses: Allergic rhinitis. Dosage: 12 - 65 years: One capsule as necessary, up to three times a day. Contra-indications: Hypersensitivity to any of the ingredients or triprolidine, hypertension, renal impairment or severe heart disease, use with MAOIs. Precautions: Diabetes, hyperthyroidism, heart disease, hypertension, glaucoma or prostatic enlargement. It is usual to advise patients not to undertake tasks requiring mental alertness whilst under the influence of alcohol or other CNS depressants. Patients taking sympathomimetics, antihypertensives, and tricyclic antidepressants. Pregnancy & Lactation: Not recommended. Side effects: Rarely skin rash, drowsiness, urinary retention or CNS excitement. Price: 12s £4.99 (£4.25 ex-VAT), 24s £8.99 (£7.65 ex-VAT). Legal category: P. PL holder: Warner Lambert Consumer Healthcare, Eastleigh, SO53 3ZD. PL no: 15513/0017. Date of preparation: March 2001. **BENADRYL ALLERGY ORAL SOLUTION** Presentation: Solution containing 1mg/ml Cetirizine hydrochloride. Uses: Seasonal allergic rhinitis, perennial rhinitis and chronic idiopathic urticaria. Dosage: Adults and children 12 years and above: 10ml once daily, Children 6 - 11 years: 10ml once daily or 5ml twice daily, Seasonal allergic rhinitis only. Children 2 - 5 years: 5ml once daily or 2.5ml twice daily. Contra-indications: Hypersensitivity to any of the ingredients. Do not use in pregnancy or lactation. Precautions: Reduce dose by half in cases of renal insufficiency. Avoid excessive alcohol consumption. Side & adverse effects: Occasionally drowsiness, headache, dizziness, agitation, dry mouth and gastrointestinal discomfort. Very rarely convulsions. Price (ex-VAT): £4.99. Legal category: P. PL holder: UCB Pharma Limited, 3 George Street, Watford, Hertfordshire, WD18 0UH. PL number: 08972/0033. Further information available from Pfizer Consumer Healthcare, Chestnut Avenue, Eastleigh, Hampshire, SO53 3ZD. Date of revision: January 2003.

Breast is officially best

Babies should be exclusively breast-fed for the first six months of life, according to new advice from the Department of Health.

The guidance says: "Breast-feeding is the best form of nutrition for infants. Exclusive breast-feeding is recommended for the first six months (26 weeks) of an infant's life as it provides all the nutrients a baby needs."

The DoH says that there are proven health benefits to breast-feeding, for the child and mother including:

- babies who are breast-fed have a lower risk of gastro-enteritis and respiratory and ear infections
- breast-fed children may be at lower risk of obesity
- breast-feeding mothers may find it easier to lose weight gained during pregnancy and have a



The benefits of breast-feeding to both mother and baby are overwhelming, according to the Department of Health

lower risk of pre-menopausal breast cancer.

A spokesman for the National Childbirth Trust said: "The evidence is clear that breast-fed babies do not generally need to start on solid foods before about six months. We are encouraging families and health professionals to have more

confidence in breast-feeding."

This advice, issued in National Breastfeeding Awareness Week, brings the UK into line with the recommendations from the World Health Organization and other countries including France and the USA.

For more information:

www.who.int/nut

Depression in primary care

In the short-term treatment of depression, tricyclic antidepressants are as effective as selective serotonin re-uptake inhibitors for patients in primary care.

The meta-analysis of studies, published in the *BMJ*, showed that there were significantly lower drop-out rates for SSRIs compared to tricyclics.

However, the authors say that drop-out rates are an "imprecise index of tolerability" as patients may stop taking medication for many reasons – not all of them due to the side effects of the medication. Although most depressed patients are treated in



SSRIs were shown to have lower drop-out rates than tricyclics

primary care, the authors found that a large percentage of studies are conducted using patients in all settings. They suggest that "since differences in the tolerability of medicines may exist between

patients treated in different settings it may be appropriate for bodies that grant licences for drugs to ensure that studies have been carried out in appropriate settings before granting specific antidepressants their licence."

- People most exposed to antidepressant drugs show the greatest fall in suicide rates, according to an Australian study in the *BMJ*. These results probably reflect improved access to treatment of depression by GPs, who prescribe most antidepressants in Australia.

For more information:

BMJ, 2003 326:1014-1017

www.bmj.com

Side effect debate over antipsychotics

Claims that the newer atypical antipsychotic drugs have a better side effect profile than conventional treatments may have been exaggerated, according to a study in *The Lancet*.

The main advantage of the newer drugs such as olanzapine, risperidone and sertindole compared to conventional drugs such as chlorpromazine, is claimed to be a reduced risk of side effects, especially extrapyramidal symptoms. However, there is a debate that the reduced side effects of the newer drugs are based on trials comparing them with high potency haloperidol.

The researchers decided to re-analyse all previous randomised controlled trials where newer antipsychotics had been compared with low potency older drugs. In a systematic review of 31 studies involving more than 2,320 patients only clozapine, a new-generation antipsychotic, was associated with fewer neurological side effects and higher efficiency than low potency conventional drugs.

Dr Stefan Leucht, from the Zucker Hillside Hospital in New York, said: "Optimum doses of low potency conventional antipsychotics might not induce

more neurological side effects than new-generation drugs. Potential advantages in efficacy of the new-generation drugs should be a factor in clinical treatment decisions to use these rather than conventional drugs. However, if these findings are confirmed by future studies, there would be a good argument for the use of appropriately dosed conventional drugs – such as chlorpromazine – for patients with schizophrenia in settings where new generation drugs are not generally affordable."

For more information:

www.thelancet.com

Scriptlines

Lipostat update

Bristol Myers Squibb has updated the SmPC for its cholesterol-lowering drug Lipostat (pravastatin), following an MCA report into muscle toxicity associated with HMG-CoA reductase inhibitors (statins).

The special warnings section now states that the level of creatine kinase above which treatment with a statin should be stopped has been reduced from 10 times, to five times the upper normal limit.

Under interactions with other medications, the SmPC now states that pravastatin is not metabolised to a clinically significant extent by cytochrome P450.

For more information:

Bristol Myers Squibb

Tel: 0800 7311 736.

BMS issues sucrose warning

Bristol Myers Squibb has updated the SmPC for Questran (cholestyramine) to include a warning over the product's sucrose content.

In the special warnings section, the SmPC now says that diabetic patients should be warned that each sachet of Questran contains 3.79g of sucrose.

For more information:

Bristol Myers Squibb

Tel: 0800 7311 736.

HRT fails to live up to expectation

Combination HRT preparations do not have a clinically meaningful effect on health-related quality of life, according to the latest analysis of the Women's Health Initiative data.

There were statistically significant effects for physical function, bodily pain and sleep disturbance but these were small and restricted to the first year of use.

For most women these benefits did not outweigh the risks of heart attack, stroke, blood clots and breast cancer associated with combined HRT use.

For more information:

NEJM, 2003, 348:19:1839-1854

www.nejm.com

Have you got the UniChem Great Business Awards all tied up?

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Which of the following have you used to publicise your business in the last 2 years?

- ☐ Newspapers ☐ Local Radio
☐ Magazines ☐ Door Drops

Have you had articles published in the local paper about your pharmacy?

YES/NO

What action have you taken to counter the OFT's proposals?

Have you:

- ☐ Written to your MP?
☐ Carried out a Business Review?
☐ Canvassed your customers?

How often do you change your shop window display?

Do you use it to reflect:

- ☐ Seasonal products ☐ Price offers
☐ TV promoted products
☐ Professional services
☐ Patient information

Do you make use of point-of-sale material in your shop? YES/NO Is this:

- ☐ Directional ☐ Promotional ☐ Category

Are there other activities you have used?
Please describe:

Professional Development

Have you undertaken any Professional Development?

YES/NO Please describe:

Have your staff undertaken any personal development activities?

YES/NO Please describe:

How frequently do you review the changing nature of your community?

- ☐ Monthly ☐ Quarterly ☐ Constantly

What professional services does your pharmacy offer?

How do you promote your professional services?

Do you run healthcare discussion groups?

YES/NO

Have you applied for or undertaken any Local Pharmaceutical Services?

YES/NO Please describe:

Have you applied for or undertaken any Local Pharmaceutical Services?

YES/NO Please describe:

Are you involved in community initiatives?

Please describe:

Business Development

How long have you owned your pharmacy?

- ☐ 1 year ☐ 2 years
☐ 3-4 years ☐ over 5 years

Have you expanded the size of your pharmacy?

YES/NO

Have you refurbished your pharmacy?

YES/NO

Have you ever done a re-launch of your pharmacy?

YES/NO

Have you extended the services you offer in your pharmacy?

YES/NO Please describe:



UniChem
Delivering Healthcare

Name
Address of business

Postcode Telephone

SERVICE + INNOVATION + EXCELLENCE + PARTNERSHIP

Entry is open to all independent pharmacists. The Awards will be independently judged. The closing date for entries is 31 August 2003. The decision of the judges is final and no correspondence will be entered into concerning the results. UniChem Ltd, UniChem House, Cox Lane, Chessington, Surrey KT9 1SN

Frontshop

Carnation steps out for the summer

Carnation Footcare products will be backed by a £250,000 press advertising campaign throughout the peak summer footcare season until mid-September.

Appearing in national daily newspapers, weekend supplements and women's magazines, the campaign will be in two parts.

The first advertisement, for Carnation Corn Caps, uses imagery of a bulls-eye on the corn to support the message 'On target to remove corns fast'.

The second part focuses on other footcare remedies – Verruca Care, APR Soles and APR Heel Pads.

A range of display material is available to support the campaign.

For more information:

Activa Health Care Ltd
Tel: 01283 540957.

ON TARGET TO REMOVE CORNS FAST

95% of corns removed within 10 days!

It's the unique corn removing paste in Carnation Corn Caps that actively treats your corns.

Clinically proven to remove corns, one pack is enough for a complete treatment. So set your sights on corn free feet.

Contains Salicylic Acid. Always read the pack label.

Get the full story on how to use Carnation Corn Caps. Visit www.carnation.co.uk

Carnation Corn Caps

- Unique corn removing paste
- 100% effective
- 100% natural

ALL IN ONE VERRUCA TREATMENT

When you use the Verruca Care product, you are using a powerful, natural, plant-based treatment to remove your verrucas. It's the only product that works on all types of verrucas.

PRESSURE RELIEF INSOLES & HEEL PADS

The unique design of the APR Soles and APR Heel Pads provides long lasting relief.

CARNATION FOOTCARE

Products available from most Boots, Superdrug, Lloyds Pharmacy and leading independent pharmacies.

For a FREE FOOTCARE INFORMATION PACK, go to www.carnation.co.uk or call 01283 540957.

A breath of fresh air from Nozone

A vaporiser for asthma sufferers is to be introduced into pharmacies by the Chemists Commercial Consultancy.

The Nozone vaporiser has been developed for asthma sufferers or anyone with a respiratory complaint such as bronchitis or rhinitis. It may also ease the symptoms caused by allergies like hayfever and help those prone to sensitisation.

The vaporiser is designed to combat the harmful effects of ground level ozone – a trigger to allergic conditions such as asthma and rhinitis.

The manufacturer says that it safely neutralises ozone from a

hazardous gas into breathable oxygen in the same way that certain trees protect themselves from ground-level ozone.

Available in two sizes (large for home, small for the car), it slowly releases a natural, lavender-based essential oil impregnated in a membrane.

The product is endorsed by the British Allergy Foundation and approved by TUV, the German quality mark organisation.

Merchandising material and product training is available for pharmacies.

Price: large £9.99, small £5.99

Chemists Commercial Consultancy
Tel: 01423 799133.

Wake up to Pro Plus

WAKE UP!

PRO PLUS

ENJOY LAST NIGHT? KEEP GOING WITH PRO PLUS

George and Mike are the stars of the Pro Plus campaign.

Roche Consumer Health is supporting Pro Plus with a poster and radio campaign this month.

Eye-catching advertising is appearing on tube card panels on the London Underground.

Characters are depicted in compromising situations where tiredness has got the better of them such as falling asleep on the toilet.

Each advertisement includes the strapline 'Enjoy last night? – Keep going with Pro Plus.'

The radio advertising features characters George and Mike discussing weird and wonderful ways of keeping awake.

For more information:

Roche Consumer Health
Tel: 01707 366000.

Antistax takes a stand

Antistax leg health supplement will be on TV for the first time throughout the summer months.

The commercial is linked to professions and lifestyles involving long periods of standing or sitting which is the principle cause of aching, heavy and tired legs.

Three high-risk professions are identified including a teacher,

health visitor and traffic warden.

The £1.3 million campaign explains how the product's red vine leaf extract can help maintain healthy leg vein circulation and combat the feelings of aching, heavy and tired legs.

For more information:

Boehringer Ingelheim Ltd
Tel: 01344 424600.

Benadryl® HAYFEVER MONITOR

For free pollen alerts text POLLEN to 85080* or log on to www.allergyadvice.co.uk

Benadryl® Allergy Relief

- ✓ No non-drowsy allergy tablet works faster
- ✓ Active in 15 minutes
- ✓ Lasts 8 hours

KEY FACTS

- Oak pollen season is at its peak in the South and is approaching its peak in the North
- 8 of the 9 AAN regions are currently on Pre-Alert, with moderate pollen levels

Benadryl® Allergy Relief

High pollen count
Medium
Low

*Text messages are updated weekly by SDI. To unsubscribe from subsequent free alerts text 'stop' to 85080.

LAMISIL[®] AT 1% SPRAY

Terbinafine Hydrochloride

Walk over the competition in just 7 sprays.

- 1 The first and only once-daily, one-week treatment for athlete's foot
- 2 Primary fungicidal from spray
- 3 No. 1 **P** brand within the category
- 4 Terbinafine gives long lasting relief for weeks and weeks
- 5 Contains the most widely prescribed antifungal for athlete's foot²
- 6 Cost effective treatment for your customers
- 7 Conveniently treats in 7 sprays – one a day for 7 days

LAMISIL[®] AT – A WINNING COMBINATION TO RECOMMEND

Also available in a cream.



Prescribing information: LAMISIL AT 1% Spray. **Presentation:** Solution containing terbinafine hydrochloride 1.0% w/w. **Indications:** For the treatment of athlete's foot, dhobie (jock) itch and ringworm. **Dosage and administration:** The spray is applied once daily for one week. Not recommended for children under 16. **Contraindications:** Hypersensitivity to terbinafine or any of the excipients. **Precautions:** For external use, avoid contact with the eyes. Avoid inhalation and do not use on the face. **Pregnancy and lactation:** Not recommended during pregnancy or lactation. **Side effects:** Redness and irritation at the site of application. Discontinue treatment if an allergic reaction occurs. **Legal category:** P. **Recommended Retail Price:** £5.49 (15ml Pump Spray). **Product licence number:** PL 0030/0147*. **LAMISIL AT. Presentation:** Cream containing terbinafine hydrochloride 1.0 % w/w. **Indications:** For the treatment of athlete's foot and dhobie (jock) itch. **Dosage and administration:** The cream is applied once or twice daily. The duration of treatment is one week for tinea pedis and one to two weeks for tinea cruris. Not recommended for children under 16. **Contraindications:** Hypersensitivity to terbinafine or any of the excipients. **Precautions:** For external use, avoid contact with the eyes. **Pregnancy and lactation:** Not recommended. **Side effects:** Redness and irritation at the site of application. Discontinue treatment if an allergic reaction occurs. **Legal category:** P. **Recommended Retail Price:** £4.99 (7.5g tube). **Product licence number:** PL 0030/0147*. ***Product licence holder:** Novartis Consumer Health, Wimblehurst Road, Horsham RH12 5AB. **Date of Preparation:** March 2003. **References:** 1. IRI Dec 2002. 2. Dinlink MAT Jan 2003.

Novartis Consumer Health, Wimblehurst Road, Horsham, Sussex RH12 5AB.

Customer Careline 01403 218111 Fax 01403 323 919 Email customer.care@ch.novartis.com Website www.comedis.com

RECOMMEND THE PHARMACISTS' FIRST CHOICE FOR ATHLETE'S FOOT

Hands up for Dove lotions

For the first time, the Dove brand is being extended into handcare products.

Dove Protective Care Hand Balm and Dove Regenerating Care Hand Cream are designed for use during the day and night respectively.

Lever Fabergé says handcare accounts for 50 per cent of usage occasions within the hand and body category.

The company believes the day and night proposition is instantly appealing to consumers as a way of expressing the functional benefits of the products.

The launch will be supported by press advertising from September as this is a key time for consumers to start buying handcare products.

A sachet sampling initiative and



in-store activity is also planned.

● Lever Fabergé hopes to drive bodycare sales in the growing skin firming sector with the launch of Dove Firming Lotion.

The product is formulated to help improve the skin's firmness

and enhance natural cell renewal. It contains ceramides and grape seed extracts, as well as the moisturisers incorporated into other Dove skincare products. Advertising support will start with a four-week TV campaign followed by press advertising throughout June and July.

Sampling activity will include the distribution of 300,000 mini bottles and 1.2 million sachets via consumer press at gyms, fitting rooms and in-store for women to try.

Both campaigns are part of a £6.5 million marketing package for Dove hand and body products.

Price: hand cream and balm (75ml)

£2.29, firming lotion (250ml) £4.99

Pip code: hand balm 293-3315, hand cream 293-3869, firming lotion 293-3299

Lever Fabergé

Tel: 020 8439 6100.



Elegance touches your nails

Original Additions is updating the image of its Elegant Touch false nail kits and French manicure products.

Featuring a metallic background and clear product descriptors, the eye-catching new packs enable easy viewing of the contents to help consumers understand the products.

The new look brings these products into line with the rest of the Elegant Touch range, providing the brand with a consistent presentation in-store.

Price: from £2.30 for Nail Glue to £10.49 for Gel Nail Kit & French Manicure Gel Nail Kit

Original Additions

Tel: 020 8573 9907.

Spray away

Sunblis International has introduced a sunburn relief spray suitable as a general after-sun product. Sunblis is formulated to reduce the pain of mild to medium sunburn and the itchiness of prickly heat.

Price: £14.95

Pack size: 250ml can

Pip code: 293-7662

Ceuta Healthcare

Tel: 01202 780558.

Bronzed and beautiful

Collection 2000 is launching a new summer cosmetics range in June.

Bronzed Beauty will feature two new products – Tinted Moisturiser and Face and Body Bronzer.

Tinted Moisturiser is formulated to provide sheer coverage and natural sun-kissed colour without the heaviness of foundation.

The product contains vitamins E and A, shea butter and wheatgerm oil plus UVA and UVB sunscreens. It comes in Sun-

Kissed and Sun-Bronzed.

Face and Body Bronzer is designed to provide all over golden colour with subtle shimmer. Easily removed with soap and water, the product comes in one shade, Bronze Shimmer.

The range also features new packaging for Shimmering Glow powder and two new shades for Plumping Lip Gloss – Sun Glow and Sunlight.

Price: Tinted Moisturiser (40ml) £2.99, Face and Body Bronzer (30ml) £2.49

Collection 2000 Ltd

Tel: 01695 727317.



Samuel Eden

Station Road, Sutton-in-Ashfield,
Notts NG17 5FQ

Son Ltd

X-Static® silver protection socks



X-Static® is permanent and performance does not diminish over time.

Silver is one of the safest substances and **X-Static®** is made with pure silver, a naturally occurring element. There are no chemicals and no fear of toxicity for the consumer.

X-Static® eliminates 99.9% of bacteria in less than one hour of exposure. Most antimicrobial products test over 48 hours and still do not reach this level of effectiveness.

The hotter and wetter the environment, the more effective **X-Static®** becomes. This is perfect, because bacteria are more prevalent in this environment.

Wearing compression hosiery can help prevent the risk of circulatory problems including Deep Vein Thrombosis. There is significant reduction of swelling and relief from tired legs.

Tel 01623 446400

www.socksonline.co.uk

Fax 01623 446500

E-mail soles@samueleden.co.uk

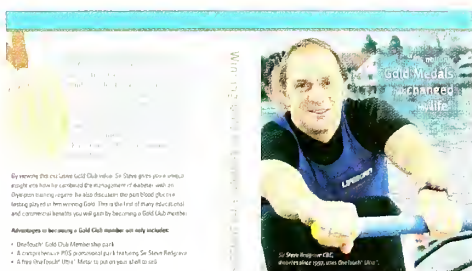
Lifescan is going for gold

LifeScan is teaming up with Sir Steve Redgrave for a new initiative targeting independent pharmacies.

Over the next month, 6,000 pharmacists will be sent a personalised video invitation from the rowing champion.

The video features an interview with the Olympian who talks about being diagnosed with the condition two years before winning his fifth consecutive gold medal in Sydney.

Pharmacists are invited to take up free membership of the Lifescan 'One Touch Gold Club' which aims to provide regular updates on blood glucose



By joining the One Touch Gold Club, Sir Steve gives you a unique insight into how he combated the management of diabetes and his experience of living with the condition. The club also offers you a free membership of the One Touch Gold Club, which aims to provide regular updates on blood glucose monitoring and diabetes care.

monitoring and diabetes care.

Gold Club members will receive a CD-Rom, health and dietary advice material and discounted terms on LifeScan's latest blood glucose monitoring device.

For more information:

LifeScan (Johnson & Johnson)

Tel: 01494 450423.



Gold Diabetes Healthcare

ON TOUCH Ultra

LifeScan

LifeScan (Johnson & Johnson)

Tel: 01494 450423.

LifeScan

LifeScan

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THE SCANDINAVIAN DETOX PLAN

No 1 in Europe!

Unique herbal detox!

BioFirm™

- Unique, natural herbal formulation
- Gentle but effective cleansing action
- Proven formulation using 10 herbs to cleanse the body of toxins
- Pack sizes: 90 tablets and 180 tablets
- National advertising campaign.



New Nordic
Pharmabrand Ltd
Phone: 0207 716 5839
Fax: 0207 716 5717

Available from:

Natrapharma	01732 860860
Supply Team	02392 472421
Tree of Life	01782 567100
Trinity	01753 864455

TVnext week

Aqua Ban: GMTV

Aquafresh: All areas except U, CTV, GMTV

Eumovate: Sat

Imodium Plus Caplets: All areas

Just for Men: All areas

Kalms: Sat E4

Listerine: All areas

Lucozade Sport: All areas except U, CTV, GMTV

Multibionta: LWT, C4

Nivea Deo Compact: All areas

Piriteze: All areas except U, CTV, GMTV

Piriton: All areas except U, CTV, GMTV

Ribena: All areas except U, CTV, GMTV

Ribena Toothkind: All areas except U, CTV, GMTV

Seabond: All areas

St Ives Facial Skincare: All areas except GMTV

Tena lady & Tena pants Discreet: All areas except U, GMTV

VO5 Shampoo: All areas except GMTV

VO5 Styling: All areas except GMTV

Zantac: All areas except U, CTV, GMTV

PharmaSite for next week: London, Midlands and East of England - **Flixonase**, the rest **Piriton** - window, W Midlands and East of England **Flixonase**, the rest **Piriton** - in-store, **Germoloids** - dispensary

A-Anglia, B-Border, C-Central, C4-Channel 4, C5-Channel 5, CAR-Carlton, CTV-Channel Islands, G-Granada, GMTV-Breakfast Television, GTV-Grampian, HTV-Wales & West, LWT-London Weekend, M-Meridian, Sat-Satellite, STV-Scotland (central), TT-Tyne Tees, U-Ulster, W-Westcountry, Y-Yorkshire

Mesalazine as a treatment for ulcerative colitis

Ipocol and Asacol: New comparative data

Ulcerative colitis

Ulcerative colitis (UC) is a chronic inflammatory disease affecting the mucosa of the large bowel and occasionally the distal ileum. The affected mucosa bleeds easily and in severe disease may become extensively ulcerated. The main symptom is diarrhoea with blood and mucus, sometimes with lower abdominal pain. Tiredness, anorexia and mouth ulcers may also be experienced. In most patients the disease follows a course of remissions and exacerbations.¹

Mesalazine

Mesalazine (5-ASA) is a standard therapy for UC, exerting its anti-inflammatory effects topically on the affected mucosa. Since immediate release formulations provide rapid and almost complete absorption of mesalazine, a variety of pro-drug and modified release formulations have been developed to target the release of mesalazine more effectively.

There are five modified release formulations of mesalazine in the UK; Ipocol® 400mg EC Tablets (mesalazine 400mg EC tablets), Asacol® Tablets, Salofalk® Tablets, Pentasa® Slow Release Tablets and Pentasa® Sachets.

Ipocol and Asacol both contain 400mg of mesalazine in a tablet coated with Eudragit S (methacrylic acid copolymer) a pH sensitive resin that is soluble in intestinal fluid from pH 7. This protects the mesalazine in the more acidic conditions found higher in the small intestine whilst allowing release towards the end of the ileum. The dosage regimen for UC is the same for the two products.

Salofalk tablets contain 250mg of mesalazine and are enteric coated with Eudragit L, designed to disintegrate above pH 6, whilst Pentasa 500mg tablets and 1g sachets both allow continuous release of drug from duodenum to rectum at all pH levels.²

Ipocol

Ipocol (mesalazine 400mg) has been available in the UK since August 2002 and is backed by over 12 years of clinical experience in Europe. Various studies have been conducted with Ipocol to investigate the site of its mesalazine release and to provide comparative data against Asacol.

In vitro data

There is currently no evidence of any direct correlation between dissolution data and the behaviour of mesalazine in man. Despite this limitation considerable interest has been raised concerning comparative dissolution profiles of mesalazine containing products.

***In vitro* release** A dissolution study³ using the method described in the Ipocol Marketing Authorisation compared three batches of Ipocol and Asacol respectively; tablets were individually tested and the mean values for each batch calculated. The results are shown in Fig 1.

- After 1 hour at pH 1.0 results for Ipocol and Asacol were identical - no mesalazine had been released for any batch.
- After a further hour at pH 6.5 results were again very similar. No mesalazine released for any batch of Asacol - between 0.1% and 2.4% for Ipocol.
- At pH 7.5 there were some notable differences between Ipocol and Asacol. Ipocol released rapidly and consistently as designed above pH 7, with results after 30 minutes of between 95.1% and 98.0%. Results with Asacol were far more variable ranging from 0.1% to 14.0% after 30 minutes and 20.0% to 49.1% after 45 minutes.

These results demonstrate that Ipocol performs as designed. The tablets are resistant to acid but allow rapid and effective release of mesalazine above

pH 7. Release of mesalazine is essentially complete within 30 minutes at pH 7.5. Inter batch variability is low.

Asacol performs in a very similar way to Ipocol up to and including pH 6.5. However, results indicate that at pH 7.5 (ie above pH 7 where the formulation is designed to release the mesalazine) only 20.0% - 49.1% is actually released within 45 minutes. Compared with Ipocol inter batch variability of Asacol is relatively high.³

The intraluminal pH of the large intestine may be below pH 7 in some patients.⁴ Tablets that have not released their mesalazine in the ileum could risk being passed in the faeces, intact. Theoretically a formulation that rapidly and extensively releases mesalazine above pH 7, like Ipocol, may confer benefits over a formulation that releases more slowly above this pH. Specific studies in man would be required to relate these *in vitro* differences between Ipocol and Asacol to their behaviour in the clinic.

Studies in man

Studies in man are generally considered to be more relevant to the clinical situation than *in vitro* studies.

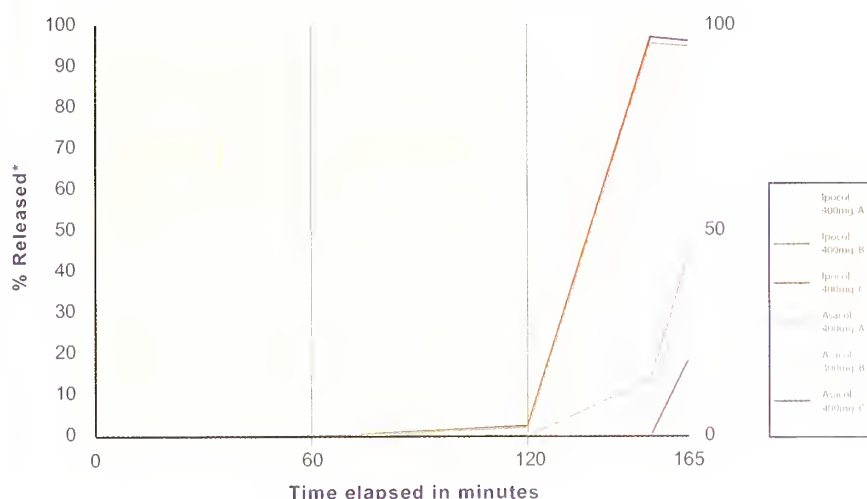
Site of release A study published in the *Scandinavian Journal of Gastroenterology*⁵ investigated the *in vivo* site of mesalazine release from Ipocol tablets* in patients. Images were taken of abdominal radioactivity using a gamma ray camera to record the transit of radiolabelled tablets through the intestines. The authors concluded that all the tablets disintegrated and released the mesalazine in the distal ileum, this was followed by the rapid spread of the mesalazine to the distal loops and the colon.

This study confirms that Ipocol acts as designed in man and remains intact until effectively releasing the mesalazine towards the end of the ileum.

* This study uses Pentacol, the Italian Trade Mark for Ipocol

Cumulative sequential release of mesalazine* from Ipocol and Asacol tablets

at pH 1 (first hour), pH 6.5 (second hour) and pH 7.5 (during third hour)



* expressed as % of 400mg labelled strength

Pharmacokinetic study A randomised, crossover, multi-dose study comparing the urinary excretion of mesalazine and its metabolite from Ipocol and Asacol, in healthy volunteers, showed that mesalazine was released and available *in vivo* by both products to a comparable extent (within $\pm 20\%$).⁶

A urinary excretion study was considered to be more relevant than a traditional bioequivalence study for this topically acting drug. 5-ASA is excreted mainly via the kidneys after systemic absorption; therefore the total amount excreted over 24 hours should correlate with the absorption of 5-ASA from the tablets. The proportion of the dose not recovered in the urine is that which remains within the gut lumen and is potentially available for therapeutic activity. The word 'potential' is important since such studies do not address whether or not the drug is completely released from the tablet.

Clinical study Interim data from a clinical study comparing Ipocol and Asacol as treatments for active mild to moderate UC indicated that there were no therapeutic differences for the efficacy variables measured. Both drugs appeared to be well tolerated.⁷

These interim results were considered to be sufficiently positive to warrant continuation of the study.

Clinical use

Ipocol was designed to act like Asacol and the two products have a number of similar characteristics.

- Both products use Eudragit S in the tablet coating which is soluble in intestinal fluid from pH 7.
- Both products can be described as mesalazine 400mg EC tablets and have the same dosage regimen for UC.
- Mesalazine was released and available *in vivo* by both products to a comparable extent (within $\pm 20\%$) in a pharmacokinetic study.

Since Ipocol may be dispensed against prescriptions calling for mesalazine 400mg EC tablets it should be noted that although Ipocol is very similar to Asacol, patients are all different. For this reason a leading gastroenterologist has suggested that whilst any change from one brand to another is unlikely to be noticed by most patients, it is probably advisable that patients are not continually swapped between brands.

Ipocol is a well established product with around 29,000 patient years of clinical experience gained over the last 12 years in Europe. It may be used for the management of any suitable patient with ulcerative colitis.

References

1. Kumar P, Clark M. Clinical Medicine (5th ed) W B Saunders; 2002.
2. Information regarding Asacol, Pentasa and Salofalk are taken from their respective Summary of Product Characteristics.
3. Data on file: Comparative Dissolution Study Ipocol vs Asacol.
4. Press AG et al. Gastrointestinal pH profiles in patients with inflammatory bowel disease. *Aliment Pharmacol Ther* 1998; 12: 673-678.
5. Sciarretta G, Furno A, Mazzoni M, Ferrieri A, Malaguti P. Scintigraphic study of gastrointestinal transit and disintegration sites of mesalazine tablets labelled with Technetium-99m. *Scand J Gastroenterol* 1993; 28: 783-785.
6. Data on file: Summary of Urinary Excretion Study.
7. Data on file: Summary of clinical study.

Ipocol is a Registered Trademark of Lagap Pharmaceuticals Ltd.

Ipocol® Abbreviated Prescribing Information

Presentation: Ipocol 400mg EC Tablets, each containing 400mg mesalazine coated with a pH dependent methacrylic acid copolymer (Eudragit S) designed to release the active drug above pH 7.0.

Uses: Treat mild to moderate ulcerative colitis and maintain remission.

Dosage: Adults; Acute attack: 6 tablets daily in divided doses, orally.

Maintenance: 3-6 tablets daily in divided doses. **Children:** Not recommended.

Elderly: Caution. Do not use if renally impaired.

Contraindications: Salicylate hypersensitivity, severe renal impairment, children under 2 years old.

Precautions: Extreme caution in renal impairment. Monitor renal function regularly, discontinue treatment if any deterioration. Stop treatment and perform blood count if suspicion of blood dyscrasias. Treat dehydration as soon as possible.

Interactions: Lactulose and other agents that lower colonic pH. Use with nephrotoxic agents may increase risk of renal reactions.

Pregnancy and lactation: Not recommended unless essential.

Side effects: *More common,* nausea, diarrhoea, abdominal pain, headache, and exacerbations of colitis. *More rarely,* reversible pancreatitis, hepatitis or abnormal hepatic function, interstitial nephritis, nephrotoxicity, myocarditis, lupus phenomenon, skin reactions including Stevens Johnson syndrome, fibrosing alveolitis. *Very rarely,* serious blood dyscrasias.

Pack sizes/cost: Blister packs of 120, £41.62. **Legal Category:** POM. **PL No.** PL 4416/0244. Lagap Pharmaceuticals Ltd, Woolmer Way, Bordon, Hampshire, GU35 9QE

Last revision of text: 14 April 2003. Ipocol is a Registered Trademark of Lagap Pharmaceuticals Ltd. Refer to Summary of Product Characteristics before prescribing. 0244 009V2

AAH

This is the seventh in a series of 10 accredited features taken from the forthcoming book, *Mind Your Own Business*, written by Dr Terry Maguire. This feature is a summary of the chapter on managing risk. The next feature will be a summary of the chapter on time management and will be published in the June 21 issue of *C&D*. The book, which is supported by Vantage Pharmacy, will be distributed to subscribers with *C&D* later this year



Managing risk

Risk is the probability of a nasty event occurring multiplied by the significance of the event if it does.

Dr Terry Maguire explains that risk management is about recognising where hazards exist, and taking steps to minimise the risk they present

Something can happen frequently but if the consequence is insignificant then the risk is small. However, when something is unlikely to happen, but if it ever did the consequences would be enormous, action needs to be taken to avoid or at least reduce the risk to an acceptable level.

In our daily lives we have a perverse approach to risk. This reflects a poor understanding of the concept of relative risk – the risk associated with one activity compared to another. Smoking is a good example. All smokers know that the habit damages their health, and that smoking presents more risk than not smoking. But smokers don't appreciate the relative risk, otherwise they would take steps not to smoke.

On the other hand, we often view things as presenting more risk than they actually do. Many people, for example, refuse to fly after high profile incidents such as September 11 despite the fact that air travel is a safe mode of transport. The relative risk of death or injury is much smaller than the risk of death or injury in a car accident.

Risk management means protecting businesses against loss, the threat of loss and the consequences of loss.

Without properly managed risk systems we are at risk of losing all manner of things – life, quality of life, wellbeing, morale, reputation, opportunity, time, resources and money. So risk management is important, but few of us take active steps to do it properly.

Where we cannot avoid risk, we must take steps to identify hazards,

appreciate the risks they present, and then take steps to minimise them. This is risk management. A risk benefit analysis is used to assess when the benefit from any activity exceeds the risk it presents.

The Committee on Safety of Medicines is routinely making this assessment on the medicines marketed in the UK. It might assess that an antihistamine medicine, which has demonstrated minor side effects, now



presents a risk to public health that exceeds its benefit. Based on this the CSM may decide to withdraw the medicine. An anti-cancer drug might exhibit some nasty side effects, but this will be judged acceptable since the cancer it is used to treat poses a greater risk.

Healthcare is a high risk industry but it has, perhaps, been less than successful in managing that risk. 'First of all, do no harm' is as relevant today as it was 2,000 years ago. Government is acutely aware of the impact of errors in the healthcare system. Each year 450,000 accidents are reported in the NHS at a cost to the service of more than £154 million.

Accidents here mean anything from a patient falling off the loo to a registrar pumping a drug into the wrong IV line. Injury is caused and compensation sought. This is money that might otherwise be used in treating patients. Clinical governance has been developed as a means of addressing the quality of clinical care in the NHS.

Clinical governance was introduced in the UK in 1999 as: "A framework through which National Health Service (NHS) organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."

Where clinical governance is about improving clinical quality, risk management has been identified as a key tool to achieving it. For the NHS, risk is a double whammy. Not only does the service have to pay compensation for clinical errors, it must also treat those injured by clinical error at additional cost to the service.

NHS organisations in both primary and secondary care have a duty of care to the public. Where a duty of care exists there is a risk that it might be breached, and where it is the service is responsible. Medication errors constitute a large percentage of these errors and this cost.

One NHS target is to reduce medication errors by 40 per cent over five years - a tall order, but possible, just! A mountain of initiatives, such as medicines management schemes and better patient information on medicines, are coming forth from the Department of Health in pursuit of this elusive goal.

While the NHS has only started to address the risk associated with the use of medicines relatively recently, risk has been a key feature of the marketing of medicine for nearly 40 years. Following thalidomide, the Medicines Act 1968 was essentially a risk management plan for the safe introduction of medicine and the

ongoing assessment of their relative risk to public health.

The public often fail to appreciate the risk associated with certain medicines. The MMR vaccine is relatively safe - but tell that to parents. The same problems have arisen with the contraceptive pill, and more recently with HRT. Medicines are rarely risk-free. How can we get this message across?

Medication errors can occur anywhere in the medicines supply system. A number of things can go wrong:

- patient gets incorrect medicine
- patient gets incorrect dose too high
- patient gets incorrect dose too low
- patient not getting a medicine
- patient getting an incorrect formulation
- poor patient concordance.

When primary care organisations get to grips with clinical governance they will require all healthcare professionals, including pharmacists, to provide evidence that they are controlling risks associated with their role. This fact will have a significant bearing on the future role of pharmacy within the NHS.

"There must be a visible first aid kit, properly stocked, and a nominated person to deal with first aid. A fire drill must be routinely conducted"

As managers we have considerable responsibility in managing risks beyond medication errors. There are risks inherent in the day-to-day running of our businesses, which brings us to health and safety legislation, a complex and far reaching area. The key piece of legislation is the Health and Safety at Work Act 1974.

This Act has spawned a mass of regulations that address specific areas of work and set out standards. For example, the Control of Substances Hazardous to Health (COSHH) Regulations (1994) and Management of Health and Safety at Work Regulations (1992) are particularly relevant to pharmacists, but there are many more, including First Aid at Work.

Each pharmacy that has more than five employees full or part time must have appointed a 'competent' person to assist in taking the necessary steps to comply with the law. This person need not be a specialist but must be aware of the requirements of the law. A manager

would do. However, ultimate responsibility remains with the employer.

The NPA offers excellent support materials to allow compliance with the law. The basic requirements are that each pharmacy has a Health and Safety Policy Statement and displays the Health and Safety at Work poster as well as a current certificate of employer's liability insurance.

You must have a detailed floor plan of the pharmacy. An accident book for recording any mishaps that occur must be available. There must be a visible first aid kit, properly stocked, and a nominated person to deal with first aid. A fire drill must be routinely conducted, sufficient fire extinguishers must be available and regularly checked. An electrical appliance inspection must be undertaken, normally annually. A COSHH assessment must be undertaken.

To develop a risk management plan start by looking at one aspect of your business at a time. This could take a number of months to complete. It is helpful to think of your business in terms of 'structure, process and outcome'. Starting off with structure, focus on the premises. Look for hazards - what risk do they present and what steps need to be taken to reduce that risk? A loose floor tile on the shop floor means there is a risk that a staff member or member of the public might trip. Action needs to be taken to fix the tile to reduce the risk - hardly rocket science.

In processes such as dispensing you might identify risks that could lead to medication errors. Having identified risks it is helpful to consider them under the headings of 'Avoid, Reduce likelihood, Transfer risk, Pay'.

Avoid

Risk should be avoided if possible. If you don't have contracts of employment for staff you are at risk of non-compliance with the law. Getting contracts of employment avoids this risk.

Reduce likelihood

Where we cannot avoid risk we need to reduce the likelihood of it occurring and if it does, ensure that the consequences are small. Having good standard operating procedures in place goes some way to ensuring that things are done properly. In general, staff training is a key element in reducing risk. Trained staff are less likely to make mistakes.

As pharmacists we always had an ethical obligation to keep up-to-date. Mandatory continuing professional development will be with us soon. This is a key element of clinical governance so it is

Continued on page 36 ►

government rather than the profession that is setting this agenda.

Transfer the risk or just pay up

Unless you can afford to pay when disaster strikes then you probably need insurance. Having the right kind and right level of insurance is a vital aspect of any risk management plan and is a legal requirement of health and safety legislation. However, in some situations insurance premiums cost so much that it is cheaper to pay up.

Insurance premiums are getting more and more expensive. Policies are also getting more complex so, although most of us do not read the small print, this is one time that you should. One of the main reasons that insurance claims are rejected is that the policy does not cover the claim.

Professional indemnity cover is essential insurance for every pharmacist. Those working in hospital might need to consider providing their own professional indemnity cover. In general, community pharmacy policies cover locums working in the pharmacy against professional error.

Critical incident handling

We must learn from errors to ensure that we don't make the same mistakes

again. But from a risk management perspective, identifying critical incidents is only the start of a process of investigation that may eventually lead to compensation being awarded to the injured party. How the incident is managed can go some way to reducing the business's exposure to paying out.

Knowing about incidents that have occurred and 'near misses' is a vitally important part of a risk management plan. An accident book must be available and accidents should be written into this book. A review of accidents can help identify risk that perhaps is not so transparent.

Getting staff to identify incidents and near misses is not easy. If staff feel they will be censured, disciplined or possibly dismissed, then they are likely to attempt to cover up incidents. There is no such thing as a 'no blame' culture in any organisation. I certainly don't feel that it is possible to allow staff the luxury of not being censured for negligent behaviour on the grounds that they own up.

However, steps should be taken to assure staff that identifying mistakes early on will possibly reduce the impact of the error on the business and as a consequence any disciplinary action taken against them personally will also be minimised.

A defined procedure for handling errors or other incidents must be a part of the risk management plan. An error, once identified, brings defensive behaviour and we can act in a way that, rather than helping the matter, makes it worse. In dealing with errors there are a number of steps to take:

- identify the staff member
- intervene
- secure medicines and prescriptions
- inform insurance company
- consider disciplinary action
- investigate.

But there may also be a need for a rapid apology: this can save much aggravation, legal costs and a hefty fine. It also maintains your reputation which can suffer when an incident occurs. Often, when no one has been injured by the incident or the injury is insignificant, this is all that people want.

Monitoring

Once a risk management plan is in place it should not become an ornament on the bookshelf, but it should be actively used. The plan should be reviewed at least annually and this date should be recorded to prove that there is a policy of review. Health and safety legislation requires this as risks change over time. ☺

Keeping safe at work...

Health and safety might not be at the top of the agenda for pharmacists busy with the day-to-day pressures of running a business. Time to call on the expertise of your wholesaler, perhaps?

Health and safety at work is an essential consideration for every business but with increasing pressures on pharmacists, finding the time and resources to pull together a comprehensive health and safety policy can be a struggle.

"Health and safety procedures in the workplace are an extremely important element of risk management. Accidents at work can be costly as they may result in personal injury, absenteeism and damage to equipment or stock," says Linda Clark, brand co-ordinator for Vantage Pharmacy.

"If pharmacies do not comply with the law, there can be other far-reaching consequences.



Local authorities are responsible for enforcing health and safety and they will periodically visit pharmacies to carry out inspections. If

necessary, they can request improvements to health and safety procedures, close down a store and even prosecute the business and individuals.



"To achieve a good health and safety culture, a number of specific issues need to be considered. The Vantage team has worked closely with pharmacists to develop a health and safety training course to offer guidance and advice on a number of important issues."

The course consists of six modules which cover a range of topic areas, from accidents in the workplace, practical exercises on risk assessment, fire damage, manual handling, young persons at work and new and expectant mothers.

"Carrying out a risk assessment is an essential procedure for every pharmacy," says Linda. "It will

highlight issues that pharmacists should be aware of such as whether fire extinguishers are available and have been tested recently, and if an accident book is available and filled in correctly. Risk assessments should be carried out on a regular basis so that any changes or lapses are noted as soon as possible.

"It is also extremely important to ensure that all staff are adequately trained and aware of health and safety procedures. Regular training courses and 'refreshers' should be organised to keep health and safety front of mind within the pharmacy."



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Jane Hutt has been reappointed minister of health and social services in Wales, following the Welsh Assembly's recent election. She will be responsible for health and NHS Wales, social services and social care, food safety, and children. The Royal Pharmaceutical Society is looking forward to continuing working closely with the minister on the development of the Welsh pharmacy strategy: "The executive looks forward to rapidly progressing the implementation plan for Remedies for Success," it said.

Edwina Hart has been appointed social justice minister in the Assembly and will be responsible for



Jane Hutt

the strategic management of substance misuse, previously with the finance portfolio.

Professor Colin Blakemore has been appointed chief executive and deputy chairman of the Medical Research

Council. He is Waynflete professor of physiology at the MRC Centre for Cognitive Neuroscience at the University of Oxford.

Shire Pharmaceuticals Group has announced that Dr Francesco Bellinin and Gerard Veilleux, both non-executive directors, have stepped down from the board on the expiry of their two-year appointments on May 10.

Straw poll puts SOS ahead

The official election of RPSGB Council members was due to close at noon on May 16 and the results will not be known until next week.

However, *C&D* has been running a non-rigorous non-scientific straw poll on our website dotpharmacy.com which may be an indicator of the official outcome. And then again, it might not.

With feelings running high among some members it is not surprising that there is a strong showing for those people standing on a 'Save our Society' soap box.

However, if extrapolated onto the non-swingometer (patent pending) without the help of Peter Snow, our poll suggests that not all seven SoS candidates will be taking their place in the Council chamber – unless as spectators.

So for those of you who can't stand the excitement any longer our just-for-fun poll has put the following seven names forward as most likely to be elected to Council on a first past the post basis:

- Doug Simpson
- Noel Wicks
- Maurice Hickey
- Bob Gartside
- Kirit Patel
- Hassan Argomandkhah; and
- Gordon Geddes.

It will be interesting to see who has made it in real life. Now, after last year's surprise challenge, does anyone want to open a book on who will be the next president?

A good run for your money

One of the people who has contributed to this page, particularly with news of appointments at Mawdsleys, has been its PR consultant Vicki Baxter.

But this time it's Vicki who can have her own moment of glory as she has managed to raise £1,300 for the British Heart Foundation. She finished the London Marathon in two hours 58 minutes, making her the 31st fastest woman in the event.

Vicki, who is a director of Baxter Hulme PR & Marketing, commented: "This was my best result ever. You know at the start that it's going to be tough. Particularly during the last six miles, but the thought that you're



Vicki Baxter – placed 31st in the women's championship race in the London Marathon

raising a lot of money for charity really does help you keep going."

Business Trends Survey winners

The latest winners in the *C&D Quarterly Business Trends Survey* prize draw have been announced.

JH Cam of the P Williams Pharmacy in Ilkeston wins the first prize of £200, CE Jay of Lavenham Pharmacy, Suffolk, wins £100, and £50 prizes go to Mrs T Evans of Cohens Chemist, Heywood, Lancs, and Alan Stockley of Smettisham, Norfolk.

Anyone wishing to be considered for the draw needs to complete one of the survey forms which are sent out to pharmacy owners or managers participating in the three-monthly survey.

For more details contact Mary Prebble on 01732 377269 or mprebble@cmpinformation.com.

The survey is sponsored by UniChem.

Read the instructions... and ignore?

Oh dear, it's happened again. The national media have picked up on the statutory labelling of medicines and poked fun at them in covering Britain's first 'Ridiculous Packaging Instructions Award'.

Nytol scooped first 'prize' but it could have been any other antihistamine-based sleep aid had the award's researchers done their work properly. Nytol, like anything else with an antihistamine, carries the statutory notice: "Warning: may cause drowsiness."

In at ninth place was Boot's Children's Cough Medicine with the warning not to drive a car or operate machinery after taking the

medication.

Just how many times a week are the labels pointed out in the pharmacy by a customer believing they are the first to spot the funny side of medicine labelling? The joke is wearing a bit thin.

Surprisingly, the awards have been set up by the Word Centre, a Sheffield based consultancy advising businesses on the use of plain English. It's hard to imagine how the labels could be written more simply.

The centre's director, David Fox, was reported in the *Sunday Telegraph* saying he hoped that national ignominy would force companies to think before they write.



Nytol: an unfair winner?

Perhaps there should be a review of the statutory labelling requirements now that several new indications have become available since the list of advisory labels was drawn up. But Mr Fox could also help persuade the public to think before they take medicines which have been purchased or supplied for other family members. Or suggest to lawyers that they should not encourage the public to be so litigious.



Doug Simpson: what are his chances in the real election?



Noel Wicks: have you backed this man?

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salicylic acid

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Bazuka is a Trade Mark and Product License held by Dicom Developments Ltd, Hitchin, Herts, SG4 7QR, UK. Distributed by DOL Ltd, 34 Hickmanworth Road, Watford, Herts, WD1 7JJ, UK. **Indications:** For the treatment of verrucas, warts, corns and calluses. **Directions for use:** For adults, the elderly and children. Once daily apply one or two drops of the gel to the lesion and allow to dry, taking care to avoid the normal surrounding skin. The following day, carefully remove the dried patch and apply fresh gel. Once every week, before re-applying fresh gel, gently rub the treated surface using the emery board provided. Continue treatment until the condition has resolved. This may take up to 12 weeks for certain verrucas and warts. **Contra-indications:** Not to be used on the face, neck, intertriginous or anogenital regions, or by diabetics or individuals with poor blood circulation. Not to be used on moles, birthmarks, hairy warts, or any other skin lesions for which the gel is not indicated. Not to be used in cases of sensitivity to any of the ingredients. **Precautions and Warnings:** Keep away from the eyes, mucous membranes and from cuts and grazes. Avoid spreading onto normal surrounding skin. Do not use excessively. Avoid inhaling vapour and keep cap firmly closed when not in use. Avoid contact with clothing, fabrics, plastics and other materials, as it may cause damage. **Side-effects:** Some mild, transient irritation may occur, but in cases of more severe irritation or inflammation, treatment should be discontinued. Bazuka Gel and Bazuka Extra Strength Gel are highly flammable - Keep away from flames. Store at room temperature, not exceeding 25°C. Keep all medicines out of the reach of children. **Legal Category:** [P] Packs: Bazuka Gel (PL0173/0161) - 5g RSP £4.95 (£4.21 exc. VAT). Bazuka Extra Strength Gel (PL0173/0154) - 5g RSP £5.75 (£4.89 exc. VAT).